

1 UNITED STATES DISTRICT COURT

2 DISTRICT OF MINNESOTA

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4)
5 In Re: Bair Hugger Forced Air) File No. 15-MD-2666
6 Warming Devices Products) (JNE/FLN)
7 Liability Litigation)
8) October 24, 2017
9) Minneapolis, Minnesota
10) Courtroom 12W
11) 9:04 a.m.
12)
13)
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10 BEFORE THE HONORABLE JOAN N. ERICKSEN
11 UNITED STATES DISTRICT COURT JUDGE

12 THE HONORABLE FRANKLIN L. NOEL
13 UNITED STATES MAGISTRATE JUDGE

14 THE HONORABLE WILLIAM H. LEARY
15 RAMSEY COUNTY DISTRICT COURT JUDGE

16 **(MOTIONS HEARING- VOLUME I)**

17 APPEARANCES

18 FOR THE PLAINTIFFS:

19 MESHBESHER & SPENCE
20 Genevieve M. Zimmerman
21 1616 Park Avenue
22 Minneapolis, MN 55404

23 LEVIN PAPANTONIO
24 Ben W. Gordon, Jr.
25 316 S. Baylen Street
Suite 600
Pensacola, FL 32502

CIRESI CONLIN
Michael V. Ciresi
Jan Conlin
Michael A. Sacchet
225 South 6th Street
Suite 4600

1 Minneapolis, MN

2 FOR THE PLAINTIFFS:

3 KIRTLAND AND PACKARD LLP
4 Behram V. Parekh
5 2041 Rosecreans Avenue
6 Third Floor, Suite 300
7 El Segundo, CA 90245

8 KENNEDY HODGES, LLP
9 Gabriel Assaad
4409 Montrose Blvd
Suite 200
Houston, TX 77006

10 KENNEDY HODGES, LLP
11 David W. Hodges
711 W. Alabama Street
Houston, TX 77006

12 FARRAR & BALL, LLP
13 Mark Bankston
1010 Lamar, Suite 1600
Houston, TX 77002

14 FOR THE DEFENDANTS 3M:

15 BLACKWELL BURKE P.A.
16 Jerry Blackwell
17 Ben Hulse
18 Mary Young
19 Deborah Lewis
20 Corey Gordon
21 Peter Goss
431 South Seventh Street
Suite 2500
Minneapolis, MN 55415

22 FAEGRE BAKER DANIELS
23 Bridget M. Ahmann
90 South Seventh Street
Suite 2200
Minneapolis, MN 55402

24 COURT REPORTER:

25 MARIA V. WEINBECK, RMR-FCRR
1005 U.S. Courthouse
300 South Fourth Street
Minneapolis, Minnesota 55415

P R O C E E D I N G S

(9:04 a.m.)

THE COURT: You have to forgive Patrick. He just found out this morning that he passed the bar, so we're the least of his worries.

Welcome. And let's just get right to it. Why don't we start with the opening statements. Defendant?

JUDGE LEARY: Judge Ericksen, if I could just clarify for the record that it is the understanding and the agreement that this is a joint session of the United States District Court as well as Ramsey County District Court Second Judicial District. If there's any -- if I'm wrong in that regard, somebody needs to speak up.

MS. ZIMMERMAN: No, Your Honor, we agree.

MR. BLACKWELL: Your Honor, you are right in that regard.

JUDGE LEARY: Okay. Thank you.

THE COURT: And I agree. Thanks very much.
Mr. Blackwell, ready to hear from you.

MR. BLACKWELL: Thank you, Your Honor.

Good morning, Your Honors, counsel. Your Honors, the Seventh Circuit perhaps said it best and as well as *In Re Bausch & Lomb* MDL court, the courtroom is not the forum to advance new scientific theories, noting that "the courtroom is not the place for scientific guesswork, even of

1 the inspired sort. Law lags science; it does not lead it."

2 I'm speaking this morning on behalf of 3M whose
3 product, the Bair Hugger, the plaintiffs have claimed causes
4 prosthetic joint infections. While the FDA and the many
5 health and patient organizations inside and outside the
6 country that have weighed in on this have expressly rejected
7 that theory, not one epidemiology study has reached that
8 conclusion, not one clinical trial has reached that
9 conclusion; all are against it. Not one biological
10 plausibility study supports that theory; all are against it.

11 Plaintiffs' own studies, their own reliant
12 studies, failed to reach the conclusion that the Bair Hugger
13 causes surgical site or prosthetic joint infections. The 3M
14 Bair Hugger has successfully warmed over 200 million
15 patients, 50 thousand patients a day. And to this very day,
16 not one treating physician has ever contacted 3M or the FDA
17 to say that they have a patient with a prosthetic joint
18 infection that was caused by the Bair Hugger.

19 So we say that 3M's -- that the plaintiffs' theory
20 is a novel theory. It is novel not only because it is not
21 generally accepted in the scientific and medical community;
22 it is novel because it has been expressly considered and
23 repeatedly rejected in the scientific and medical
24 communities. Not one valid scientific study reaches the
25 conclusion that the Bair Hugger causes prosthetic joint

1 infections, not even the plaintiffs' own studies, and
2 plaintiffs' experts here have not conducted even one study
3 of their own that reaches a different conclusion.

4 This is litigation science, plain and simple,
5 promoting a novel scientific theory of the Bair Hugger
6 causing infections when it's unsupported and uniformly
7 rejected outside of litigation in the so-called real world.
8 Why in the world would this Court want to give speculative
9 science, these Courts give speculative science to a jury to
10 reach a scientific conclusion that stands rejected by both
11 the FDA and the weight of the whole scientific and medical
12 communities? What purpose would that serve? And what kind
13 of chaos and confusion would that create in the scientific
14 and medical communities for doctors and patients alike?
15 That would be the epitome of the law leading the science and
16 not lagging it.

17 This should not be such a thing as litigation
18 science that stands out front and in stark contrast to the
19 general accepted science in the real world. Plaintiffs have
20 to have science outside of litigation, testing the end point
21 of whether the Bair Hugger causes surgical site infections
22 or prosthetic joint infections and finding that it in fact
23 does. They do not.

24 Scientific theories that have only been considered
25 in the general scientific community, considered and rejected

1 in the general scientific community, automatic never to go
2 to a jury for the purpose of establishing counter
3 propositions or to reach findings that go beyond the
4 peer-reviewed studies. Your Honors should be extremely
5 skeptical about a so-called science generated for the first
6 time in litigation and equally skeptical of any litigation
7 attempts to, in quotes, blue pencil or re-characterize the
8 current body of the scientific evidence to recast it as
9 somehow supportive of causation when they expressly said
10 that it isn't.

11 And to be clear, Your Honors, this is not a weight
12 versus admissibility issue that's at stake here. For there
13 to be a weight versus admissibility issue, there must be
14 something that constitutes weight under Rule 702. Under
15 *Glastetter*, that weight must be scientifically valid proof
16 of causation in order for that to get to a jury. Generally
17 rejected scientific theories should not constitute weight.
18 Reliant studies that expressly and uniformly do not find a
19 causal relationship between the Bair Hugger and infections
20 should not constitute weight. Causation theories that live
21 and breathe only in litigation expressed by litigation
22 experts who have never publicly expressed those opinions
23 anywhere else should not be weighed. If the best that can
24 be said of the plaintiffs' scientific theory is that it is
25 generally not supported by the scientific community, that

1 has to be the virtual near opposite of valid scientific
2 proof of causation in fact. No general acceptance in the
3 peer-reviewed literature and no general acceptance in the
4 medical community should equal no weight, should equal no
5 admissibility.

6 The science upon which the plaintiffs' scientific
7 or medical case relies is unreliable, inherently unreliable,
8 because it is litigation driven, litigation created, has
9 been uniformly rejected in the scientific community outside
10 of this court, and it has severe methodological flaws to the
11 extent it is resting overwhelmingly on the McGovern study
12 and I'll also say the Augustine 2017 study.

13 And so why this is so important, Your Honor, is as
14 the Court said in a different MDL, *In Re Lipitor*, because
15 expert witnesses have the potential to be both powerful and
16 quite misleading, "It is crucial that the District Court
17 conduct a careful analysis into the reliability of the
18 expert's proposed opinion." Wonderful opinion that's in
19 many respects on all fours with this case, *In Re Lipitor*.

20 I want to tee up for just a second this issue of
21 biological plausibility. The general causation question
22 here is whether the Bair Hugger causes prosthetic joint
23 infections, not whether it moves air around or moves
24 particles or that sort of thing. The claim is that it
25 causes infections, that simple, bacterial infection. They

1 don't have even minimal facts or data that the Bair Hugger
2 is capable of releasing bacteria into the operating room or
3 moving bacteria to the surgical site, let alone prove that
4 it can cause a prosthetic joint infection.

5 There have been over the past 25 years, going back
6 to 1991, Your Honors, some nine different studies, the
7 latest of which is just this year, looking at this question
8 of biological plausibility, and every one of them concluding
9 the same thing that they could not find or culture any
10 bacteria coming from the Bair Hugger blanket when it's being
11 used properly, but the point is that not biological
12 plausibility itself gets you across the analytical gap
13 between the plaintiffs' proof and valid evidence of
14 causation to pass the Daubert muster. Plaintiffs don't have
15 a single biological plausibility study even supporting the
16 propositions that they state here.

17 MAGISTRATE JUDGE NOEL: Let me just ask this
18 question, if I could, two questions. First of all,
19 throughout the papers there are reference to prosthetic
20 joint infection, surgical site infection, and deep joint
21 infection. For our purposes today, are those -- I
22 understand that there are differences, but for purposes of
23 determining whether these experts are admissible or not, are
24 those synonymous?

25 MR. BLACKWELL: Yes, Your Honor, from the

1 prosthetic joint infections are just a subset of surgical
2 site infections, and our view is that plaintiffs don't have
3 any science supporting either one.

4 MAGISTRATE JUDGE NOEL: Okay.

5 MR. BLACKWELL: So it becomes merged in, there
6 being no data there.

7 MAGISTRATE JUDGE NOEL: And then my second
8 question is, as I understand it, there has been no clinical
9 studies, that is, blind, whatever you're calling the gold
10 standard, of this very question, whether the Bair Hugger
11 does or doesn't cause these infections.

12 MR. BLACKWELL: Your Honor, there were two. I'm
13 sorry, please.

14 MAGISTRATE JUDGE NOEL: Wouldn't it be in 3M's
15 interest to conduct such a study? And if so, why has such a
16 study not been done?

17 MR. BLACKWELL: Your Honor, we'll point out and
18 we'll talk about this more fully in the context of
19 discussing the medical causation experts, but starting in
20 1991 there were two clinical trials done then where patients
21 were compared, those receiving warming from the Bair Hugger
22 to those receiving no warming, and those studies concluded
23 that not only was there not an increase in surgical site
24 infections, that in fact it decreased the incidence of
25 surgical site infection, and that was done early on.

1 And I might add further, Your Honor, in terms of
2 just the burden of proof -- and so the immediate answer to
3 your question is those studies have been done even before 3M
4 bought an interest in this particular product and company in
5 2010, so they had been done some nearly 10 years or plus
6 before, 20 years before.

7 And but the second part of this answer, Your
8 Honor, is that the plaintiffs have the burden to show that
9 to the extent their experts are making these claims that
10 they've got to bring forward that evidence, and we will show
11 to Your Honors that organization after organization,
12 including the FDA, has looked at all of the scientific
13 literature and concluded uniformly that there is no basis
14 for a claim in science that the Bair Hugger is causing or
15 contributing to cause either surgical site infections or
16 prosthetic joint infections. So -- I'm sorry, Judge
17 Ericksen.

18 THE COURT: As long as you're already interrupted,
19 is there any brief response you would like to make, you
20 mention the *Glastetter* case, and as you know, the plaintiffs
21 have criticized your reliance on the *Glastetter* case in
22 their papers. Is there any response that you would make to
23 the criticism that *Glastetter* is not so good to rely on?

24 MR. BLACKWELL: Only, Your Honor, that the Eighth
25 Circuit relies on it, and that's good enough for me, and

1 it's been relied upon by many courts in this circuit and
2 outside since it was decided. So I think the plaintiffs'
3 position is probably more characterized as not liking the
4 *Glastetter* opinion, Your Honor, but it's not that it's
5 somehow bad law and is somehow make per curiam tantamount to
6 some unpublished and unreliable. And it would be news to
7 the Eighth Circuit per curiam shouldn't be relied upon by
8 courts in this circuit.

9 THE COURT: I think they were talking about the
10 medical certainty standard.

11 MR. BLACKWELL: Well, the *Glastetter* opinion is
12 very clear in the interpretation of Daubert that there must
13 be scientific ly valid proof of causation, and the
14 *Glastetter* court was even clearer in talking about those
15 scientific proofs have to show causation in the real world,
16 not theoretical animal studies, textings, and so on to show
17 that there is impact in the real world, so those were
18 presented in *Glastetter*, rejected by *Glastetter* court,
19 ultimately concluding that they were not valid scientific
20 proof of causation.

21 And the language in *Glastetter* that the plaintiffs
22 are referring to related to the particular drug involved
23 there where they claimed it caused vascular constriction,
24 where the Court said that there was no scientifically
25 convincing evidence that this drug causes vascular

1 constriction. That's what the *Glastetter* court in fact said
2 in quotes. And so the plaintiffs may feel that they don't
3 have to meet the burden set forth in *Glastetter*, but the
4 Eighth Circuit didn't say that.

5 THE COURT: Thank you.

6 MR. BLACKWELL: So, Your Honor, getting back to
7 the type of evidence that the plaintiffs have here, I was
8 talking about biological plausibility as sort of an interim
9 sort of a screening, because not even biological
10 plausibility gets you across the hurdle into proper
11 scientific valid proof of causation, and many courts have so
12 held in causation cases such as this, but the plaintiffs
13 don't even have that.

14 So what they're relying on are these tertiary
15 secondary endpoint exploratory studies, studies that involve
16 bubbles and particles and had the beginnings of smoke
17 studies and studies that expressly disclaim causation, and
18 they don't even demonstrate, as I said, biological
19 plausibility. So what are they relying on here? They're
20 relying on those what I call smoke particle -- well, bubble
21 and particle studies. They also rely on animation, a CFD.
22 And no court we could ever found --- could ever find this
23 computation of fluid dynamics animation. We never found a
24 court that's found that a computer animation, especially an
25 unvalidated one, is a substitute for even showing biological

1 plausibility, much less causation in the real world.

2 They rely on the McGovern study, and we're going
3 to dive deep into McGovern, Your Honors, because at no
4 matter what level you look at the McGovern, on the surface
5 it is -- it is flawed on the surface. It's flawed for the
6 reasons that Your Honors have already acknowledged that it
7 has many confounders that were not were controlled for and
8 never even considered, but as we plunge the depths of it, we
9 hope to share, and my colleague Cory Gordon who spent quite
10 a bit of time in the UK digging this out will come up to
11 talk about how that McGovern data is in fact cooked, it's
12 manipulated data, it's flawed data, it was manipulated when
13 the data went from Dr. McGovern and got into the hands of
14 Dr. Scott Augustine and his consort, and they essentially
15 manipulated the numbers to try and influence statistical
16 significance, and we can show that to Your Honors as an
17 additional reason why the McGovern study is hopelessly
18 flawed.

19 In the context of McGovern, we also want to talk
20 to Your Honors about the Augustine 2017 study. This is a
21 study that the plaintiffs were for until they were against
22 it, and they were for it and volunteered it, Dr. Samet,
23 their expert, at his deposition as additional reliance
24 material. Sorry, Judge Noel.

25 MAGISTRATE JUDGE NOEL: I have this feeling of

1 déjà vu all over again. It seems to me that in the context
2 of the motion on punitive damages, I thought everybody
3 agreed that the 2017 Augustine study was a non thing, that
4 it wasn't going to be relied upon by either side.
5 Defendants were attacking it; plaintiffs said we're not
6 going to rely on it. I thought it was a dead letter, yet it
7 does show back up in footnotes of the memos and you just
8 mentioned it, so is it a thing or not a thing?

9 MR. BLACKWELL: Your Honor, it is a thing to this
10 extent. It's a thing to the extent that apart from what the
11 lawyers said, Dr. Samet himself volunteered at his
12 deposition that part of what he was relying on as bolstering
13 his opinion was the Augustine 2017 study. That's the first
14 thing.

15 The second thing is what it reveals about the
16 motivation behind the manipulation of the McGovern data
17 because the same authors were involved in Augustine, the
18 2017 study. And we can show Your Honors fairly clearly
19 enough that that was, in fact, again, a fraudulent study
20 that was sent through the peer review process claiming that
21 the Bair Hugger performed poorly at certain hospitals and
22 that we learned in affidavit said they didn't even use the
23 Bair Hugger. And there was a motivation to cook that data.
24 And the same authors transferred over to McGovern went
25 through the same thing. And so what we simply want to show

1 Your Honors that what's at bottom here is scientific or at
2 least science being used for marketing purpose and being
3 manipulated and being falsified for purposes unrelated to
4 good science, and so we want to spend just a little time on
5 August 2017 just to make the -- Augustine 2017 to make the
6 transition to McGovern to show it's the same individuals
7 that engaged in the same conduct with the same motivation
8 and the outcomes are just the same. And it also we think
9 should cast greater skepticism on the overall reliance on
10 McGovern given that baked within it is the sort of
11 dishonesty that's part of a scheme, and that's why we want
12 to talk about it.

13 So, again, Your Honors, as we say, this is not a
14 weight versus admissibility issue, this is profoundly a
15 fundamental gatekeeping issue.

16 So, Your Honors, as I say, very familiar with
17 McGovern, we're going to spend a lot of time talking about
18 McGovern because it's Dr. Samet who said that McGovern is
19 the only study that -- and here's what he said, the McGovern
20 paper supplies the only estimate of the risk associated for
21 deep joint infections associated with the use of forced air
22 warming Bair Hugger device, so absent the quantitative
23 estimate from that paper, while it may be a quite plausible
24 mechanistic basis for increased risk, there would not be an
25 association in the real world.

1 And so we focus on McGovern because it's the only
2 real world study that the plaintiffs purport to rely upon,
3 and it's a very fragile study. Part of the reason I want to
4 give Your Honors the backdrop and history of the motivation
5 is that it is so fragile that the difference of simply one
6 surgical site infection put over a HotDog column of the
7 study taken away from the Bair Hugger impacts statistical
8 significance, even just one.

9 MAGISTRATE JUDGE NOEL: Let me just interrupt
10 there because this is question has recurred through all the
11 memos and this appears to be an opportune time to ask it,
12 although perhaps you're going to tell me I should hold my
13 question until you get to whoever is doing McGovern.

14 MR. BLACKWELL: I don't think I'm allowed to, Your
15 Honor.

16 MAGISTRATE JUDGE NOEL: In your papers you say
17 repeatedly that when you account for the confounders,
18 including what you're describing now is a
19 mischaracterization of one of the infections, the
20 association between infection and Bair Hugger disappears
21 entirely.

22 MR. BLACKWELL: Entirely, Your Honor.

23 MAGISTRATE JUDGE NOEL: Yet throughout the papers
24 there's this more detailed reference where as I understand
25 McGovern concludes that it's like a 3.8 times risk of

1 infection using Bair Hugger and then the plaintiffs go
2 through a bunch of arithmetic, and I believe I've seen this
3 also in your papers acknowledging that it goes from 3.8 down
4 to 2.76. How does that disappear and what am I missing in
5 those two different factoids?

6 MR. BLACKWELL: Your Honor, so going to the 2.76
7 is simply trying to correct the math in the first place,
8 putting the confounders aside, because the 3.8 itself is not
9 an accurate number according to the person who did the math
10 in terms of what appeared in there. So there's a huge fight
11 or argument over what is the actual data and will the real
12 McGovern data please stand up, and we believe that we can
13 show Your Honors that the data we have is the real data.

14 And furthermore, to that point, a hopelessly
15 flawed and confounded study that the plaintiffs compound by
16 arguing that the data is flawed doesn't really help them to
17 prove that it's that much reliable given that the data is
18 supposedly confound and flawed, but once the express or
19 known confounders are controlled for, mostly the
20 ant clotting medication and the antibiotic, even Albrecht
21 who did the number crunching and was one of the study
22 authors of McGovern, says that the statistical significance
23 or difference is reduced to zero once the confounders are
24 controlled for. So there are issues over the basic math and
25 whether the math is cooked. I don't think there's a single

1 debate or discussion anywhere in this case that once those
2 confounders are controlled for that that number becomes
3 zero. I don't think that's disputed and --

4 THE COURT: Did you say that they're not
5 confounders, they're not real confounders, separate studies
6 show that it doesn't matter what clotting you use so it
7 doesn't matter if you switch the antibiotic?

8 MR. BLACKWELL: That's right, Your Honor. And
9 that's what example of what I referred to as sort of the
10 blue pencil approach to this is as to simply say the
11 confounders aren't really confounders, and so that is not
12 what the peer review has concluded, that's not what's
13 generally accepted in the scientific literature. And with
14 all due respect to the plaintiffs on that regard, they
15 really are just whistling ipse dixit when they make that
16 claim.

17 THE COURT: Did you just make that up?

18 MR. BLACKWELL: It felt good, Your Honor.

19 MAGISTRATE JUDGE NOEL: This is the first case, I
20 was just amused as I'm reading through the papers, the first
21 case I can think of in my 28 years on the bench where I've
22 actually had occasion to use and understand and actually
23 apply in context the phrase ipse dixit.

24 MR. BLACKWELL: You'll get a lot of practice here
25 too, Your Honor. Even the argument that the 3.8 odds ratio

1 is so big that it could not have resulted from chance,
2 completely made up. There's nothing in the scientific
3 literature that says that a 3.8 odds ratio is so big that
4 you don't have to consider confounders. There is no
5 reputable analytic approach to the science where confounders
6 shouldn't be considered. Lots of ipse dixit here.

7 So when we get into the deeper dive on McGovern
8 and the numbers, I will tell Your Honors ahead of time it
9 will -- the space will get a little weedy. We tried to make
10 it condense, but it's important to see, you know, where the
11 flaws are in the data that underlie all of this. And, as I
12 say, Mr. Gordon will go into that in greater detail.

13 But Your Honors are very familiar with the fact
14 that the FDA has weighed in on the issues that are pending
15 in this lawsuit and the FDA letter that came out on
16 August 30th of 2017, and they did this having reviewed the
17 science, being aware of the claims in the lawsuit, having
18 looked at the literature. They even looked at the so-called
19 fake MDR's that were discussed in the Court as well that
20 were purportedly, in one instance, sent by Dr. Gothey. We
21 find out it was stated by Dr. Gothey; they were being
22 written in fact by Scott Augustine, and they looked at those
23 too. And the FDA concluded, after a thorough review of the
24 available data, the FDA has been unable to identify a
25 consistently reported association between the use of forced

1 air thermal regulation systems and surgical infections.

2 What this is really relevant to and underscores is
3 what is the state of the art in the general scientific and
4 medical community? The FDA is certainly adds this voice to
5 a consistent body of studies that have all uniformly found
6 that there's no science supporting a causation.

7 MAGISTRATE JUDGE NOEL: You mention in your paper
8 that this paper came out after the FDA became aware that
9 certain hospitals were reluctant to use forced air warming.
10 How did the FDA become aware of that and what process did
11 the FDA go through in generating this August letter?

12 MR. BLACKWELL: Well, Your Honor, the FDA became
13 aware in large part because of all of the publicity around
14 the lawsuits filed here in this MDL, from MDR reports, and
15 other reports filed by Scott Augustine to the FDA that have
16 been involved in investigations of claims submitted to the
17 FDA about this for years, and reached the point now where
18 physicians were starting to make decisions about patient
19 care based upon the kind of allegations that are being made
20 here that the FDA does not find any real basis for in the
21 real science out in the real world and so they wanted to
22 give directions to the physicians and patients, and this was
23 the outcome.

24 MAGISTRATE JUDGE NOEL: So was anybody at 3M
25 involved in notifying the FDA that decisions are being made

1 by doctors based on this claim?

2 MR. BLACKWELL: 3M, Your Honor, was involved, at
3 least the FDA did investigate and question 3M, as they did
4 Scott Augustine.

5 MAGISTRATE JUDGE NOEL: Sua sponte or 3M asked
6 them to investigate and interview us?

7 MR. BLACKWELL: No, 3M did not ask FDA to
8 investigate and interview. 3M asked the FDA to investigate
9 the claims that Scott Augustine was making around the
10 science, and we will show Your Honors that as late as 2012,
11 with respect to the McGovern study alone, the FDA wrote to
12 Scott Augustine and asked him to stop making representations
13 that the McGovern study showed that efficacy of this
14 product, the HotDog, was good evidence that the Bair Hugger
15 performed relatively poorly in comparison to it is the best
16 answer I can give Your Honor, but this has been all over
17 from TV broadcast that some of the plaintiffs' firms in here
18 have been associated with. It's just been into the news, as
19 one might expect.

20 MAGISTRATE JUDGE NOEL: But isn't this letter,
21 this August letter from the FDA, somewhat unusual to just
22 sua sponte come out with a position in a case that is
23 clearly a major piece of litigation?

24 MR. BLACKWELL: It's unusual, Your Honor, in a
25 case of unusual things. It's unusual to have a case of this

1 sort where there are claims of causation where the
2 plaintiffs' own studies don't support causation. It's
3 unusual for there to be this public kind of uproar and over
4 an issue that no scientific, valid scientific study
5 supports. And so if the public starts to get worked up by
6 claims, by advertisements, et cetera, this comes to the
7 attention of the FDA and because there is no science and
8 uniformly no science supporting it, they took a position
9 because it becomes a matter of patient safety and care and
10 physicians not knowing what to do in light of this. So
11 ultimately, Your Honor, so the -- as Your Honors know, the
12 FDA recommended the continued use of thermal regulating
13 devices.

14 And I will say too if the plaintiffs have some
15 evidence that they want to point to, anything that 3M gave
16 to the FDA or anyone else can be gotten through a FOIA
17 request, and if there's any kind of basis for a claim that
18 3M did something improper with respect to the FDA beyond,
19 you know, rumor, I'd love to hear it because we don't know
20 about it.

21 So I'll stop with this, Your Honor, because this
22 *In Re Bausch & Lomb* case is on all fours with this case in
23 many ways, where the Court there found plaintiffs cited no
24 published peer reviewed or scientific literature concluding
25 that moisture lock is related to an increased rate of

1 non-Fusarium infections because there is none. No medical
2 or scientific organization or board, epidemiological or
3 anecdotal study has associated non-Fusarium infections with
4 moisture lock use. That case, same as this case.

5 In sum, plaintiffs' theory is an educated guess.
6 And there it's the same with respect to this case. There is
7 no study that the plaintiffs have that's a gold standard
8 study that's showing that the Bair Hugger causes surgical
9 site infections. They don't even have biological
10 plausibility studies at all.

11 And Your Honors may wonder, given how easy it is
12 to test for biological plausibility, in taking up on Judge
13 Noel's question earlier about 3M's testing, that simply was
14 the simplest way, getting a little agar plate of petri plate
15 and just setting it out and trying to capture bacteria and
16 culture it. How simple and how cheap is that to do? You'll
17 find that not one of these very highly credential experts
18 did that one time and will come in and tell the Court the
19 results. And given that, given how simple it is, should
20 cast some degree of skepticism on the science that they're
21 in fact promoting as proof of causation.

22 And we will show Your Honors in fact that the
23 exploratory study, the particles, the air movement and so
24 on, were studies that were concocted by Scott Augustine and
25 what he and his cohort Mr. Albrecht referred to as the

1 Augustine publication factory, and those studies were never
2 designed to establish whether the Bair Hugger causes
3 surgical site infections; those were studies designed to
4 completely avoid the question to get results they could use
5 for marketing purpose, and we'll show that to Your Honors
6 too. It's completely unreliable, disreputable, and not
7 trustworthy. Thank you, Your Honor.

8 THE COURT: Thank you, Mr. Blackwell.

9 And Mr. Ciresi.

10 MR. CIRESI: May it please the Courts, I presume,
11 counsel. Let me address at the outset the FDA question that
12 was raised by the Court. I'd love to know what 3M said to
13 the FDA. What they responded in a specific objection to a
14 request is those documents are not relevant to the parties'
15 claims or defenses. The deadline for general causation fact
16 discovery has passed and plaintiffs have not sought leave to
17 take out of time discovery. A pattern of --

18 JUDGE LEARY: Mr. Ciresi, are you suggesting that
19 the FDA bulletin or letter to physicians or the interested
20 health care providers was cooked in and of itself?

21 MR. CIRESI: I have no idea whether it was cooked.
22 I'm not accusing the FDA of cooking something. I am aware,
23 going back to Dalkon Shield to Mirapex, that there has been
24 case after case after case and product after product has not
25 been provided full, complete transparent information. I

1 don't know what 3M said to them. Do I believe that the FDA
2 in and of itself cooked its communication? No. And I'm not
3 suggesting that. What I am suggesting is that we don't know
4 what 3M said and we cannot find out because they don't want
5 us to know.

6 JUDGE LEARY: It strikes me as the most important
7 thing is whether or not in the estimation of the FDA its
8 report or bulletin was reliable, and it seems to me that
9 you're conceding that, from the FDA's point of view, it was
10 reliable.

11 MR. CIRESI: What was reliable?

12 JUDGE LEARY: Its report and its advice to
13 physicians and hospitals.

14 MR. CIRESI: What was this report, Your Honor?
15 What did it say?

16 JUDGE LEARY: Well, you have it.

17 MR. CIRESI: Well, what it said was that the --
18 can't identify consistently reported association between
19 forced air warming and SSI's. It didn't --

20 JUDGE LEARY: Having looked at the available
21 literature.

22 MR. CIRESI: It didn't talk about prosthetic
23 infections which goes to a previous question. There is a
24 difference between deep joint infections and SSI's. I can
25 get an SSI because you, the doctor, after the operation,

1 engaged in negligence with an unclean changing of the
2 dressing, all kinds of things --

3 JUDGE LEARY: Let me stop you, Mr. Ciresi. You're
4 saying that this report had nothing to do with prosthetic
5 surgeries, but the very reason why this report was issued is
6 because of the controversy that was being generated with
7 regard to forced air warming devices and prosthetic
8 surgeries.

9 MR. CIRESI: Your Honor, what you have to look at
10 is what the FDA says.

11 JUDGE LEARY: I just paraphrased what they said.

12 MR. CIRESI: Paraphrased it. You have to look at
13 the language --

14 JUDGE LEARY: Mr. Ciresi, the impetus for the
15 report was because of the controversy that had developed
16 relating to the use of forced air warming devices and
17 prosthetic surgeries. That's the reason they issued it. So
18 it you want to parse the difference between prosthetic
19 surgeries and a common variety of surgical site infections,
20 that is not in -- that is not in that report.

21 MR. CIRESI: That's what the data is about. There
22 hasn't been -- you asked about whether -- one of the Judges
23 asked about whether there's been a study, a particular
24 study, there hasn't been. 3M did not do it. It was
25 recommended that they do it by Dr. Sessler.

1 JUDGE LEARY: All I'm talking about is what the
2 FDA did, and they said that they looked at available
3 literature, the --

4 MR. CIRESI: Your Honor --

5 JUDGE LEARY: -- issue that was in controversy.

6 MR. CIRESI: Yes, and they do not have a study
7 that looks specifically at that issue. Now, as long as
8 we're on epidemiology, I was going to get to that second.
9 I'm here for two purposes. Number one, what are the
10 material evidentiary facts which establish the general
11 factual construct underlying and underpinning the motions
12 before Your Honors; secondly, the role of epidemiology in a
13 general causation context. And that's precisely, Your
14 Honor, where you're at right now.

15 The role of epidemiology, statistically
16 significant epi studies, are not required for causation in
17 the scientific world. Epi studies prove associations, don't
18 prove causation. Much has been made in the punitive damage
19 orders and other places that this study disclaims causation.
20 That is normal in an epidemiological study. Statistical
21 significance does not show causation. In fact, you could
22 have statistical significance and there wouldn't be a
23 causation. It doesn't address that issue at all. It talks
24 about the probability of chance. That's all it does. It
25 doesn't suggest there's causation in a given situation or

1 not.

2 MAGISTRATE JUDGE NOEL: But I'm looking at page 31
3 of your memo -- I'm sorry, page 25 of your memo and talking
4 about McGovern.

5 MR. CIRESI: Which memo, Your Honor?

6 MAGISTRATE JUDGE NOEL: Good question. This is
7 the one -- the memo in opposition to exclude Samet, Jarvis,
8 and at the top you say the study authors, meaning the
9 McGovern study authors, the study authors also testified
10 repeatedly that they continue to stand behind their findings
11 that Bair Hugger increases the risk of DJI, deep joint
12 infection.

13 And I guess that caused me to ask a question,
14 because then further down we talk about associations, and I
15 thought the whole point was that nobody claims that McGovern
16 proves causation. What McGovern shows is an association
17 between the use of the Bair Hugger and a 3.8 times higher
18 rate of deep joint infection. And I guess my question is,
19 doesn't this line suggest that by saying that the authors
20 stand behind their findings that the Bair Hugger increases
21 the risk is a statement of causation, isn't it?

22 MR. CIRESI: No, it's not. It's a statement of an
23 increased risk. A relative risk is risk in exposed versus
24 risk not exposed. It doesn't necessarily say there's
25 causation. It is an element under Bradford Hill criteria

1 that should be taken into account if one is following valid
2 scientific methodology in arriving at a conclusion of
3 causation.

4 MAGISTRATE JUDGE NOEL: Okay. So just so that I'm
5 clear, the study authors don't go beyond McGovern. McGovern
6 simply still stands for the proposition and plaintiffs only
7 put it forward for the proposition that there is an
8 association between the use of Bair Hugger and the incidence
9 of infection?

10 MR. CIRESI: It stands a little bit more than
11 that, Your Honor. You're right as far as you went, but it
12 shows an increased risk, relative risk. Even when you take
13 into account confounding variables that risk is lower, but
14 it's still over two. Now, the mere fact you're over two
15 does not mean there's causation, and I would never stand in
16 front of you and say that. For 47 years I've been trying
17 these types of cases. There's a reason why medical
18 treatises are not given to the jury. Under 803.18, they're
19 not. Now, statements of a manufacturer are given to the
20 jury because they should judge the credibility of what
21 they're saying. They look at those underlying facts. A
22 medical treatise is examined through an expert witness. And
23 there are confounding variables in every epidemiological
24 study. The only study -- you asked, does 3M ever do a
25 study. The study was recommended to them. They have a

1 protocol for it. I took the deposition of the individual.
2 They haven't done it. They won't do it.

3 MAGISTRATE JUDGE NOEL: Nor have you, correct?

4 MR. CIRESI: No, we haven't. Oh, so that's a very
5 good point. No, we haven't. So that what you're saying is
6 that not the manufacturer who is presumed to know it has a
7 legal duty to know more than anybody else about their
8 product does not have to do the study but an injured person
9 out in the field who gets the product used on them should do
10 the study?

11 MAGISTRATE JUDGE NOEL: Well, yeah, because you're
12 the plaintiff, and that is sort of the way our legal system
13 works, it's your burden to establish causation, correct?

14 MR. CIRESI: Yes, but we don't have to do that
15 type of study to establish causation, and we're not required
16 to do that type of test to establish causation. If there
17 was -- you know, Judge, if we look back at epidemiology and
18 go back to Henle Koch, okay, tuberculous, cholera, those
19 tests are different. There's different types of causality.
20 There the causal factor is necessary and sufficient to prove
21 causation because that's all it does. If it's removed, you
22 don't get it. That evolved into the 20th century to the
23 Bradford Hill, and Bradford Hill frankly arose out of
24 cigarettes. It dealt with lung disease and smoking. And as
25 the science developed, what the medical world did, an

1 epidemiologist did, is they say you look at other factors.
2 You take in the fact these criteria. And that's what I
3 would like to get at, the criteria that are present in this
4 case and I think the factual underpinning of how Your Honors
5 are going to have to look at the issues before you.

6 These facts are agreed to, frankly, by all the
7 witnesses, the chain of infection, the biological
8 plausibility. Gary Hansen, who was at Arizant and its
9 predecessors from 2001 to 2015, was the director of research
10 and development from I believe 2006 through '13. Before
11 that he was the director of advanced technology. He had an
12 ongoing responsibility for engineering of the product. He
13 established policy. He was at a high level. He made
14 planning level decisions. He knew the probability of injury
15 and he was indifferent to it, and his evidence is
16 uncontroverted. Chain of infection, all present in the Bair
17 Hugger and its environment of use.

18 And I believe this is critically important. Any
19 product liability case looks at two things, first of all,
20 you identify the hazard as an engineer and then you look to
21 how you eliminate that hazard, if there is a hazard, and it
22 depends upon its probability of reoccurrence, how severe the
23 injuries may be if that does occur, et cetera.

24 What did Mr. Hansen testify to on the chain of
25 infection with the use of the Bair Hugger in its normal

1 operating condition? The pathogens or the bacterias are
2 present, fomites are present. Fomites mean particles,
3 non-living particles that carry bacteria, and there are
4 studies that prove that and they're not going to deny that.
5 These particles can be clothes, skin, all kinds of
6 non-living objects. There's a means of transmission with
7 the Bair Hugger. That's the air flow. The pathogens are
8 viable. There's a susceptible host.

9 And here Mr. Hansen went into detail of the
10 environment of use. You have compromised patients. They
11 may even have diabetes which are more compromised, and he
12 knows that. They could be obese which creates another risk,
13 and they know that. They know that the environment in the
14 operating room has pathogens in it. They know the purpose
15 of liamor flow. They know that you should reduce the level
16 of particles to the greatest degree possible, not increase
17 them, in the area of the surgical site. Testified to all
18 that, the susceptibility of the host. And he knows, most
19 importantly, in deep joint infections, which is different
20 than SSI's as a generic term, that a small bolus of
21 bacteria, very small, one or two pathogens, can cause
22 injuries that, in his words, are catastrophic. He knew all
23 that. They never tested the product to see whether
24 pathogens come out of the distal end, never.

25 And what do they tell the courts? Augustine, it's

1 Dr. Augustine, we've spent more time on Dr. Augustine, I
2 salivate at the opportunity to cross-examine Dr. Augustine.
3 Salivate because nothing was done to test this device.
4 510(k) predicate was the wetland, the Sweetland bed warmer,
5 wasn't even used during surgery. That was the 510(k)
6 predicate, and that's how you can get a device from an FDA,
7 Your Honor, under the market, no testing whatsoever.

8 He mentions one study, Zink. Zink, those were
9 only eight people. 25 percent of them, a quarter, had
10 bacteria in the dish at the surgical site. Well, he said
11 there was another study. He couldn't even pronounce the
12 name. It was the co-author of Zink. That's all they did.
13 That's all they did.

14 Now, when you look at this in the simple context
15 of what's the hazard and how do you eliminate it and what
16 did they do, in other words, what did they know, when did
17 they know it, and what did they do about it, it becomes very
18 simple to look at the context of this case and what the
19 facts are from which a jury is entitled to make a
20 conclusion.

21 We give Your Honors, as we do in all these cases,
22 reams of documents and paper saying there's no genuine issue
23 as to any material fact. And it takes I don't know how many
24 trees to suggest there isn't. Well, the facts here are
25 pretty direct, and when you analyze the epidemiology in the

1 context of that, then you find that there is a chain of
2 infection here known to this defendant, nothing done to
3 change it, and that infections are happening. The study
4 that can be done, the bacteriology study, has not been done,
5 as I suggested earlier by 3M, even though it's been
6 suggested by their consultants. If brakes could fail on a
7 car and it was due to a defect, would anybody suggest that
8 the manufacturer shouldn't remedy that defect regardless of
9 how many times it happened?

10 In case after case of drugs or medical devices,
11 you will find that it's the manufacturer that has all the
12 information. Epidemiological studies are almost impossible
13 to conduct on all of these. The power of the studies that
14 are needed are enormous. It costs millions of dollars to do
15 these studies. That's why Bradford Hill criteria are used
16 to determine causation. You really think that a doctor who
17 goes in and makes a differential diagnosis says, oh, is
18 there an epidemiological study? And then all they're going
19 to rule on that and I'm not going to say there's a cause
20 unless I have that? No. They use the epidemiology as an
21 element, as part of the components of making a
22 scientifically valid conclusion and judgment. That's what
23 we have in this case.

24 The testimony of Hansen, which I've highlighted,
25 is repeated, Your Honors, by Michelle Stevens Hulse, by

1 every deponent that I took, every one. There's no
2 disagreement here. The fact is this device has a chain of
3 infection pathway, no different than other products that
4 have been out there, and nothing was done to correct it.
5 And it's not necessary, there are alternative ways to warm a
6 patient which is another element that's considered as to
7 whether someone acts willfully, intentionally, or just
8 negligently. There's no doubt that the actions of this
9 defendant were deliberate and intentional, none, based on
10 the testimony of their high-level managers.

11 Epidemiology, and on I believe it's page 2 of the
12 motion to exclude our experts is where they use the same old
13 myth that they've been throwing up to these two courts
14 constantly, that's McGovern. And they say this, Ultimately
15 plaintiffs' experts fall back on just one uncontrolled
16 observational study to support the opinions that the Bair
17 Hugger system increases the risk of DJI. It's not true.
18 It's false. And my colleagues as they address each one of
19 the experts in this case, Dr. Samet, Dr. Jarvis, and Dr.
20 Stonnington, will go into that in greater detail. It simply
21 isn't true.

22 But as I said earlier, and I think this is --
23 excuse my frustration, Your Honors, but epidemiology has
24 been so misused by so many people, courts have been so
25 misled, and, frankly, a lot of decisions are based on the

1 advocacy in front of the courts and rightfully so because
2 the courts can't do it all themselves. That's why the
3 manual says that epi is not necessary to prove causation.

4 Statistical significance is only a tool. It is
5 not the determination of causation. The tradition of
6 scientific explanation requires that an assertion of proof
7 of cause and effect must specify the mechanism by which the
8 effect is produced. Here, it is present and agreed to by
9 everyone, the chain of infection. There's a temporal
10 association which is one of the most critical Bradford Hill
11 criteria. There is a strength of association. That's
12 McGovern. And you can argue about that. That's what it's
13 about. That's what happens from that witness stand.

14 Mr. Blackwell goes into detail about how, well,
15 you know it's 3.8 but then it's reduced to 2.8 but it's
16 really not 2.8 because of this. All right, let's see how
17 those experts stand up under the test of cross-examination.
18 I wish that all three of you could have observed the
19 depositions of -- just the ones I took because I can't speak
20 for the other ones, I wasn't there, but I wish you could,
21 you know, you could see what they said and be able to judge
22 their credibility. That's what these people do, the jury.
23 That's what's happening here. And we're arguing over
24 inferences and conclusions that should be drawn by a jury so
25 long as we have valid, scientifically credible opinions, and

1 they are.

2 The statement that only McGovern is relied on is
3 belied just by John Samet. Dr. Samet is one of the
4 preeminent world experts in epidemiology. He relied on over
5 200 sources. Ms. Conlin will get into that in greater
6 detail.

7 THE COURT: Just before you leave McGovern, would
8 it be a relevant factor at all whether the study authors
9 stood to gain financially from the results of this study?
10 How would that factor in?

11 MR. CIRESI: Your Honor, if I were answering that.

12 THE COURT: I'm asking you.

13 MR. CIRESI: I know, and I am going to answer that
14 and whether I was answering here or anyplace, I would say of
15 course it's relevant. It's a factor that should be taken
16 into account by the trier of fact.

17 THE COURT: Well, let's assume, because we have a
18 couple of days set aside for Daubert hearing, that the Court
19 does have a gatekeeping role.

20 MR. CIRESI: I'm not denying that.

21 THE COURT: And so my question is what, if any --
22 I mean, how -- first of all, was there a financial interest
23 in the outcome of the McGovern study?

24 MR. CIRESI: I don't know. Not that I'm aware of,
25 none.

1 THE COURT: And if there had been, how would the
2 Court use -- what would be the appropriate --

3 MR. CIRESI: Let me answer that with a
4 hypothetical question which I think answers it, and that is
5 that if 3M does a study which they have the protocol for,
6 they haven't done yet, would their financial interest be a
7 factor that should be considered? Yes. In every study
8 that's done where someone gets -- some investigator gets
9 money from a company or an organization, they're required to
10 disclose it.

11 THE COURT: I think Ms. Conlin wanted to speak to
12 you about whether there's any evidence of a financial --

13 MS. CONLIN: I was just going to say that the lead
14 author Dr. McGovern -- excuse me, Your Honor -- lost money,
15 so there was no financial interest in the McGovern study.
16 These individuals didn't work for Augustine or anyone else,
17 and I'll get into it in more detail during my presentation.

18 THE COURT: Okay. Mr. Ciresi, my question --

19 MR. CIRESI: Judge, can I ask, is your question in
20 terms of -- let's just speak hypothetically, in terms of
21 financial motivation, is it -- does Your Honor's question go
22 to should you exclude a piece of evidence based solely on --

23 THE COURT: That's an overly simplified question.
24 As you know, the cases talk about one of the things that a
25 gatekeeping court can take into account is whether science

1 is litigation based, and would that same caution extend to
2 studies where there is a financial interest in the outcome
3 of the study?

4 MR. CIRESI: I think that it is a factor -- I
5 don't think. I know it is a factor that one should consider
6 whether one is functioning in the role of gatekeeper or
7 finder of fact.

8 THE COURT: So my question then specifically on
9 the McGovern, if there's no financial interest, I was struck
10 when I read the study at the end, it says the author or one
11 or more of the authors have received or will receive
12 benefits for personal or professional use from a commercial
13 party related directly or indirectly to the subject of this
14 article. And my question is what -- how -- what are we to
15 do with that in the context of our directive to take into
16 account whether a study is for the purpose of litigation and
17 if financial benefit is to be considered in a similar way to
18 litigation study, the statement right there in the study
19 that the author or authors will receive personal or
20 professional benefit?

21 MR. CIRESI: I just want to take a look at the
22 statements.

23 MS. CONLIN: Your Honor.

24 THE COURT: I just -- we have -- I have to hear
25 from -- if you want to talk to Mr. Ciresi, but we just got

1 one at a time. But did you want to go ahead and talk to
2 Ms. Conlin, Mr. Ciresi?

3 Page 9 of -- 9 of -- well, I don't know if you
4 have a copy of it, but just before the references.

5 MR. CIRESI: I don't see it here, Your Honor.
6 Just let me see if I can consult with Ms. Conlin.

7 It's right at the very end right after the
8 supplementary materials, that's the one you're talking
9 about, Your Honor?

10 THE COURT: Yes.

11 MR. CIRESI: Yep. The author of one or more, I
12 believe, and I will let Ms. Conlin clarify this when she
13 gets up to argue this part of it, but I believe that refers
14 to Mr. Albrecht who was working part-time, I believe, for
15 Augustine when he was matriculating toward his degree and
16 was being paid by him, I believe that's what it was. So
17 what I say to this is that as this goes back to the point I
18 raised earlier, and that is that in any medical study,
19 because of the fact that there were in the past, as Your
20 Honors know, secret studies, secret studies paid for by
21 other people that had an interest in it and it was not
22 disclosed.

23 THE COURT: In this case?

24 MR. CIRESI: No, no, generally so that the
25 practice and the rule is that you should disclose any type

1 of potential economic connection so that a gatekeeper or a
2 trier of fact can take that in account if they decide to
3 based on the balance of the study and whether it is a study
4 that follows valid scientific methodology. Now, if it
5 doesn't and it's highly speculative and it's nothing but
6 conjecture and the person that's being paid for it, whether
7 it was conducted by 3M or anybody else, I would imagine that
8 would be taken into account.

9 The type of scientific principles that I've talked
10 about in my time here, Your Honor, and I'll close with this,
11 Your Honors, are the ones that were followed by each one of
12 the experts of the plaintiffs. It is precisely that
13 scientific reasoning and methodology that has been proven
14 reliable and valid over time across a wide range of products
15 and issues regarding associations and causation, and that's
16 what they utilize in framing their opinions in this case.

17 And for any lawyer to stand in front of a court
18 and to suggest or imply that one needs an epidemiological
19 observation study that proves causation or establishes
20 causation is to exhibit a profound lack of understanding of
21 what epidemiology is about. There are, as I said earlier,
22 confounding variables in every study. It's just by it's
23 nature there are apparent associations that are not
24 statistically significant may nevertheless be causal and
25 those that are statistically significant may not be casual.

1 Indeed, the test of significance, as I reference,
2 does not even address the issue of whether an association is
3 causal or whether it's due to some error resulting from the
4 study's design, its interpretation, or the conduct of the
5 study itself. And that is what is evaluated on that
6 component, but that's only one element of a causation
7 opinion. And as I said, that's why Dr. Samet, for one,
8 relied on over 200 sources. Yes, Your Honor.

9 MAGISTRATE JUDGE NOEL: So as I understand the
10 defendants' world view of this case, they want us to believe
11 that your case depends entirely on two questions. One,
12 whether McGovern is valid science; and two, whether
13 particles are an adequate substitute or proxy for bacteria.
14 Just in 25 words or less, is that wrong? In other words,
15 are they right that if McGovern goes out and particles are
16 not proxies for bacteria, you don't have a case?

17 MR. CIRESI: No.

18 MAGISTRATE JUDGE NOEL: And why not?

19 MR. CIRESI: Because bacteria can get there in a
20 number of ways, not just on the backs of particles, if you
21 will. There is no doubt of how this machine works, none.
22 And there's no doubt in anybody's mind that one or two
23 bacteria, one or two bacteria can cause a deep joint
24 infection because it creates the biofilm and it festers for
25 a long period of time. It's different than other types of

1 infections.

2 In the Mirapex cases which were in this district,
3 they're for Parkinson's diseases. It was for Parkinson's.
4 And the MDL was here. It was effective for Parkinson's but
5 it also caused abnormal behaviors because it was a dopamine
6 antagonist and it worked on the part of the brain that
7 created hyperactivities in certain areas. They knew it.
8 They never warned about it.

9 Now, that isn't to say that Mirapex couldn't be
10 used for Parkinson's, but they should have warned about it
11 because they knew about it. This device may be good for
12 other types of infections -- or surgeries, I should say,
13 excuse me. It isn't for this type of surgery. That's what
14 we're saying. And not because of one study, Your Honor, or
15 that a bacteria can ride along, if you will, on particles,
16 no, for the whole totality of the Bradford Hill criteria
17 inherent in the experts' opinions that have been proffered
18 for Your Honors. That's the best way I can answer that,
19 Your Honor. And I apologize it was more than 25 words.

20 MAGISTRATE JUDGE NOEL: It was more than 25 words,
21 but it answered my question so thank you.

22 MR. CIRESI: Thank you, Your Honors.

23 THE COURT: Thank you very much. All right.
24 Defendant's motion to exclude SJS, the medical experts. So
25 is this you, Mr. Blackwell?

1 MR. BLACKWELL: Yes, Your Honor.

2 THE COURT: Will you be talking about -- are we
3 going to go Samet, Samet, Jarvis, Jarvis, Stonnington,
4 Stonnington? Or are you going to Samet, Jarvis, Stonnington
5 and they're going to come back with Samet, Jarvis
6 Stonnington?

7 MR. BLACKWELL: I'm going to do Samet, Jarvis,
8 Stonnington together.

9 THE COURT: As you briefed them.

10 MR. BLACKWELL: And I think they want to kind of
11 segregate them out.

12 THE COURT: All right. Why don't you go with
13 yours, and they can talk about them in whatever order they
14 want. But we'll -- so basically we'll hear from you, and
15 then we'll hear from them.

16 You should sometimes come to one of these judge
17 conferences filled with really old people and there's ding,
18 ding, ding, ding, ding, none of us know how to turn off our
19 stuff. I might have told you that story before.

20 All right. Mr. Blackwell.

21 MR. BLACKWELL: Thank you, Your Honor. I stand
22 here to argue our motion to exclude the opinions of
23 plaintiffs' medical causation experts Samet, Jarvis and
24 Stonnington. Our argument is largely premised on their
25 reliance on the McGovern study as the only real world study

1 they have that shows an impact in the real world. Our view
2 is that those opinions are based upon completely unreliable
3 data to the extent they premised in McGovern, to the extent
4 premised in the exploratory studies, CFD, studies about
5 particles, air movement, etc., those exploratory studies are
6 completely insufficient proof to bridge the analytical gap
7 between -- around the science plaintiffs have and the
8 science they're required to put on to meet the Rule 702
9 requirements.

10 As I mentioned in the opening, Your Honors, for
11 the McGovern specific aspect of this I'll ask my partner
12 Corey Gordon to speak to just McGovern because that is -- he
13 developed McGovern. I want to speak to the general state of
14 the science and the fact that the plaintiffs' view and
15 theory of the science is generally rejected in the
16 scientific and medical community.

17 I wanted to take a couple things out of order,
18 just to set the table a little bit, because there was a lot
19 said again about this SSI versus PGI issue, and I want to
20 pull up a slide that might be the Rosetta Stone that kind of
21 gets to the bottom of this, if I could pull up number 37.
22 And what this is, is international consensus meeting, as
23 Your Honors can see, and that of the prosthetic joint
24 infection, and so this is an international consensus meeting
25 that is about PJI.

1 And let's see what they have to say. This is from
2 October 22nd of 2013, and this group met in light of the
3 kinds of things that came out of McGovern and so on, and but
4 who is this organization? Four hundred delegates, the
5 world's best experts in musculoskeletal infection from 52
6 countries and 160 societies. 300 of the 400 delegates
7 attended the meeting and were involved in voting, and the
8 consensus processes, Your Honors, to meet there took over
9 10 months, and they purported to have turned over every
10 stone in search of evidence to these questions with over
11 3500 related publications evaluated and most certainly
12 McGovern.

13 I wanted Your Honors to see this in terms of who
14 was there, delegates from various disciplines, orthopedic
15 surgery, infectious disease, and as you can see the rest of
16 these, towards the end it says, Numerous scientists with
17 interests in orthopedic infections came together to evaluate
18 evidence when present or reached consensus regarding the
19 current practices for management of SSI slash PJI.
20 Discussed interchangeable, kind of one and the same. And so
21 the evidence, when available, has been assessed, otherwise
22 the cumulative wisdom of 400 delegates from 52 countries and
23 over 106 societies has been amassed to reach consensus about
24 practices.

25 So what they address is a question that's central

1 to why we're here. There were over 300 delegates there at
2 the face-to-face meeting there for the voting, and wanted to
3 have Your Honors to see what the strength of consensus means
4 before we show you what the consensus vote was. And Your
5 Honors can see that at number 3, a super majority strong
6 consensus is a consensus where there's 66 to 99 percent
7 agreement, so just, you know, a category short of unanimous.
8 So the information available in this document is based on
9 evidence, whenever present, or the result of cumulative
10 wisdom of over 400 of the world's experts.

11 So here is the question that they were addressing,
12 SSI slash PJI, do forced-air warming blankets increase the
13 risk of surgical site infections? Consensus, "We recognize
14 the theoretical risk posed by forced air warming blankets
15 and that no studies have shown an increase in surgical site
16 infections related to the use of these devices. We
17 recommend further study but no change to current practice."

18 And that was a strong consensus, position, point
19 of view even in the face of McGovern. So this argument
20 about SSI suddenly meaning something is superficial as
21 opposed to a PJI which means deep joint infection, with all
22 due respect, is insignificant that's created primarily by
23 the lawyers in this courtroom and not by anything that's
24 found in the literature that simply discuss PJI as a subset
25 of SSI. And here where we have this international consensus

1 meeting of prosthetic joint infection, experts, doctors,
2 etc., by the hundreds strong consensus position that there's
3 no evidence there to support it.

4 MAGISTRATE JUDGE NOEL: Well, 90 percent of --
5 almost 90 -- 89 percent agreed with the statement that they
6 recognize a theoretical risk and that further study is
7 recommended, right?

8 MR. BLACKWELL: Yes, Your Honor. And so further
9 study recommended, meaning that the current state of the
10 science today doesn't support a valid claim for that -- for
11 that risk. Theoretical is never going to be sufficient to
12 pass muster onto Daubert. There must be something that
13 shows there's a real world effect. And like anything else
14 that as far as science knows today, this substance is not
15 dangerous but we always continues to study things. But the
16 danger is in having litigation lead science by having
17 outcomes in the court of law that don't exist out in the
18 scientific world. And here you have a strong consensus by
19 those who are concerned about prosthetic joint infections as
20 well as SSI's.

21 I wanted to clarify one other thing related to the
22 Bradford Hill criteria or the Bradford Hill factors.
23 Bradford Hill factors are not factors that can be used to
24 serve to the basis for the valid science establishing a
25 positive cause -- positive association or causation in the

1 first instance. You only reach Bradford Hill factors after
2 there's been a valid finding of a positive association.

3 If I could pull up number 79. And this is from
4 the reference manual in scientific evidence at pages 598 and
5 599. The authors of the *Reference Manual on Scientific*
6 *Evidence* emphasize that the Bradford Hill factors are
7 employed after a study, and that's in the text in italics,
8 "only after the study finds association to determine whether
9 that association reflects a true causal relationship."

10 In the context of McGovern, the best that can be
11 said about that study is that it disclaims there being a
12 causal basis for the positive association found due to, it's
13 clear about it, the uncontrolled confounders that are
14 addressed in that study. Or should I say not addressed in
15 the study but referenced in the study, Your Honors.

16 So this isn't simply a matter of no epidemiology
17 study making a finding of a causation. This is not about
18 generalities. The specifics of the McGovern study is that
19 it is clear why it is limited and it's clear on its face
20 it's because the, of amongst other things, the confounders
21 that were not controlled for, wasn't even a randomized
22 study.

23 So I'll show Your Honors in a moment how McGovern
24 has actually been discussed in the broader general medical
25 and scientific communities and the very interpretation here

1 that plaintiffs are espousing that it somehow can be used to
2 get a pair of scissors and a pacepot and cut out the most
3 positive association and rip it from its context, has been
4 rejected in the general scientific medical communities.

5 THE COURT: Just help me -- my memory of the
6 McGovern study. I know that some of the confounders that
7 were discussed were the ones that have proof that don't
8 really matter. Did it also talk about -- I just remember in
9 the plaintiffs' brief they were critical of a list of non --
10 obesity.

11 MR. BLACKWELL: Yes. Fitness for surgery.

12 THE COURT: Right.

13 MR. BLACKWELL: There's a whole list of those
14 confounders which still were not addressed, and there's been
15 plenty --

16 THE COURT: And did the McGovern study itself
17 acknowledge that the obesity group of factors also was not
18 taken into account?

19 MR. BLACKWELL: Yes, it does, Your Honor. And as
20 Your Honor notes in the punitive damages order that just
21 came out, it does take into account, and it makes a
22 reference that's to the effect of those confounders could
23 have also impacted the outcomes, the positive association
24 seen in the McGovern study.

25 THE COURT: Right, right, right. I'm just looking

1 -- right. But that is in the McGovern study somewhere,
2 isn't it?

3 MR. BLACKWELL: It is, and so as it says, Your
4 Honor, that I think at pages 5 and 6, McGovern says
5 unfortunately the study was neither randomized nor
6 controlled for variables identified elsewhere as important
7 predictors for deep infection.

8 THE COURT: I remember the sentence that starts
9 "unfortunately," so it's in there, okay.

10 MR. BLACKWELL: It is in there, Your Honor, and
11 the types of health factors, co-morbidities, that Your Honor
12 is referring to were included in that list, I think it's
13 around pages 5 and 6 of the McGovern study.

14 Now, so I want to move away from Bradford Hill for
15 just a moment, but we don't reach Bradford Hill unless
16 there's already established good scientifically valid proof
17 of causation, at least a positive association, before we can
18 cross the bridge to Bradford Hill. And it's not to be used
19 to launder or otherwise insubstantial, not competent
20 opinions to launder through Bradford Hill and then they
21 suddenly come out strong and fortified proof of causation.
22 So the scientific manual on evidence says that these factors
23 are to be employed only after a study, a valid study, finds
24 an association, and here, there isn't any.

25 There can be arguments from all day that lawyers

1 can create about pathways to infection, and what's important
2 from a scientific point of view is not the description of
3 the pathway but the description of what its destination is
4 and what it proves when it arrives there. Does it prove the
5 Bair Hugger produces surgical site infection? And there is
6 no study that does that. Are there types of studies that
7 could? A proper observational study, if we could pull up
8 number 54, so again, from the *Reference Manual of Scientific*
9 *Evidence*, that observational studies provide good evidence
10 in the following circumstances: The association seen in
11 studies were different designs on different kinds of
12 subjects and done by different research groups. That
13 reduces the chance that the association is due to a defect
14 in one type of study, a peculiarity in one group of
15 subjects, or the inaccuracies of one research group. And so
16 it is calling for the study of more than just one generally
17 and that particularly the one study, such as McGovern,
18 that's hopelessly confounded, there are ways to do proper
19 observational studies. There, the plaintiffs do not have
20 any.

21 So if I may, Your Honors, returning to the
22 beginning, so to speak, as to why it is we focus on
23 McGovern, I won't dwell on this much because Your Honors
24 have seen it and heard it, and, again, this is what Dr.
25 Samet has said, the McGovern paper supplies the only

1 estimate of the risk associated for deep joint infection
2 associated with use of the forced air-warming Bair Hugger
3 device, so absent the quantitative estimate from that paper
4 it would be -- while there would be a quite plausible
5 mechanistic basis for increased risk, there would not be an
6 association in the real world but for McGovern. And we
7 might add, we volunteered his reliance on Augustine 2017.
8 Dr. Jarvis, was there any other study that you referenced in
9 your report that purported to show a relative risk of Bair
10 Hugger versus some other warming modality in terms of joint
11 infections? No. He was being asked about McGovern, that
12 was -- the solid one was McGovern. Dr. Jarvis, Your Honor,
13 didn't take into account the confounders in McGovern
14 whatsoever. He just simply took the conclusion, the
15 positive association, and went down the road.

16 And Dr. Stonnington was a little back and forth,
17 so we ask him about McGovern, and he said, I'm going to say
18 that you have to put them, McGovern and the other studies,
19 together to make a conclusive argument. And he said I think
20 what's conclusive is the Bair Hugger is dangerous.
21 Augustine, I mean, McGovern is a very important study, very
22 important findings, increased infection rate in patients
23 with Bair Hugger, which I believe to be true, which I
24 believe his findings to be true.

25 So Dr. Stonnington particularly is basing his

1 opinion on his own ipse dixit, and to the extent there's any
2 science at all that's verifiable, repeatable, it doesn't go
3 anywhere beyond simply, again, McGovern. And, again, Dr.
4 Stonnington doesn't address the confounders whatsoever
5 either.

6 One of the critically important things about each
7 of these three experts, their credentials notwithstanding,
8 is that the opinions they're expressing about the infection
9 and Bair Hugger are being expressed for the first time in
10 the context of this litigation. They never published that
11 anywhere before. I couldn't find a speech where they ever
12 said that. These are opinions being expressed for the first
13 time in litigation.

14 So turning to the general causation question,
15 whether the Bair Hugger causes prosthetic joint infections,
16 and what is the generally accepted view in the scientific
17 community on this question? So I wanted to walk Your Honors
18 through that by first talking about certain types of
19 studies, and I won't spend much time on them because these
20 studies don't exist in the plaintiffs' hopper to meet their
21 burden.

22 But, first, I have some agreement about what the
23 patient warming benefits are, Your Honor, I wanted to put
24 this up first. And so here is what the various studies
25 would be addressing. The benefits of the Bair Hugger that's

1 shown to not increase but to decrease surgical site
2 infection, to decrease the incidences of fatal heart
3 attacks, of blood transfusions, length of hospital stay,
4 post-operative shivering, and those are the benefits of
5 intraoperative warming, the benefits of the Bair Hugger. So
6 when you talk about patient warming generally, it, to me,
7 can't be ignored that the overwhelming majority of patients
8 in America are being warmed by the Bair Hugger, well in
9 excess of 70 percent of them.

10 So what's the gold standard for epi studies? The
11 gold standard in the testing of pharmaceutical or other
12 agents is a randomized, double blind, cohort study in which
13 the control and intervention groups are perfectly matched.
14 There won't be any of that in this. There are no gold
15 standard or either epidemiology studies beyond McGovern that
16 plaintiffs rely on. For clinical studies similarly
17 randomized trial, clinical trial or true experiment is
18 considered the gold standard for determining the
19 relationship. And as Your Honors can see here what the
20 standard is for the gold standard in clinical studies.

21 So I wanted to just touch on for just a moment
22 what the primary endpoints are and sort of the hierarchy of
23 studies, how do they all fit? You know, the primary
24 endpoint of being infectious, studies that show in the real
25 world the Bair Hugger causes infection. These secondary

1 things don't quite get you there. There's still an
2 analytical gap between increased bacteria between --
3 deposition of bacteria in the wound, correlation of bacteria
4 with species in the wound, those are the so-called
5 biological plausibility studies. And then a step below
6 those are counting particles, presence of bacteria on
7 surfaces, et cetera, air temperature differences, et cetera,
8 we call tertiary, and those fall short of also.

9 As so Your Honors can see, I've also just stated
10 that but a different way from biological plausibility on
11 down. And I showed you these to point out that plaintiffs'
12 studies all fall within this bottom category, exploratory
13 studies that lack clinical relevance and have no predictive
14 value. The most you're going to get from a study counting
15 particles is a hypothesis for doing another study. It
16 doesn't actually prove causation.

17 And what I will show Your Honors is that when
18 these exploratory studies were done, the particle counts and
19 so on, that these studies were in vision at the time to
20 establish something other than proof of causing surgical
21 site infections. And I'll show you when those were first
22 kind of masterminded by Scott Augustine and along with Mark
23 Albrecht who's at the root of all the studies that
24 plaintiffs rely on and you can go to right to the epicenter
25 when he's talking about them and what they intended to show

1 and what they're not intended to show, meaning surgical site
2 infections.

3 So if we look at the clinical studies, to Judge
4 Noel's question earlier, there was Kurtz and Melon, two of
5 those, one in 1996, another in 2001 that were comparing
6 patients warmed with Bair Hugger to patients who weren't
7 warmed at all. And this is where -- and these clinical
8 studies, clinical trials, the conclusion was that the Bair
9 Hugger actually reduces surgical site infections, all of has
10 been made about what 3M didn't do. This was done. Tests
11 were done, peer-reviewed studies, and there they are.

12 Biological plausibility studies, all of these
13 studies which are testing whether or not there is an
14 increase in bacteria in the operating room or they can
15 culture bacteria from the Bair Hugger blanket have been used
16 properly. Mr. Ciresi just spoke about how expensive, how
17 frightfully, terribly, horribly expensive it would be for
18 the plaintiffs and the experts to have to undertake a study.
19 It's as simple as getting a petri dish, putting a petri dish
20 and agar plate in the room, turn it on, it's designed to
21 catch and capture bacteria, and so easily could have gotten
22 one of those for less than a hundred dollars and so
23 certainly would not have cost them, you know, tens of
24 thousands of millions, Your Honor.

25 So these studies have been done. Three, six, nine

1 of them, one as late as this year, where they are testing
2 whether or not you could culture viable bacteria from the
3 Bair Hugger. These studies we think are extremely
4 significant to the argument over particles. Particles are
5 substitutes for actual bacteria.

6 And this case I can't say enough is not about
7 abstractions, whether abstract in the environment of use and
8 abstract in the environment of use in the OR there particles
9 and particles carrying bacteria. The question related to
10 the general cause question here as to whether the Bair
11 Hugger causes surgical infections is whether there have been
12 any studies that have examined particles from a Bair Hugger
13 and have actually been able to culture any bacteria from
14 those. Not theoretically, not abstractly, but in fact.

15 And not only have there been not nine studies that
16 have looked at since from 1991, all of which have come back
17 and said no, there have been so-called secret studies that
18 Your Honors will learn that the reason we end up with these
19 exploratory studies of particles and bubbles and so is
20 because they first tried in the secret studies could not
21 culture any bacteria in the room or in the agar plates and
22 so it didn't want to do that again and so it turned the
23 sites into doing things they could train and use as proxies
24 for marketing purposes, and that's how those studies came
25 about that are the plaintiffs' additional reliance studies.

1 And it's avoiding the biological plausibility question.

2 And I wanted to just show you all, Your Honors,
3 this OB study because it just came out this year where the
4 question was airborne bacterial contamination during
5 orthopedic surgery with a normalized control pilot trial.
6 And Your Honors can see here it was a peer reviewed that
7 showed no association between Bair Hugger use and increase
8 in airborne bacteria. And this study compared airborne
9 bacteria sampling results between the HotDog and the Bair
10 Hugger system during -- and in orthopedic surgeries, and the
11 authors concluded it was not possible to detect any higher
12 bacterial counts on any plate in the forced-air warming
13 group versus the resistive warming group.

14 And it goes on to say that patients were
15 randomized which there was no randomization in McGovern,
16 with excel random numbers to intraoperative warming with
17 either of the systems. This is simply how they went about
18 the study. And important finding in that study was the type
19 of patient warming did not influence the amount of bacterial
20 sedimentation on either plate.

21 MAGISTRATE JUDGE NOEL: Who sponsored this study?

22 MR. BLACKWELL: Your Honor, it was done by a
23 Dr. Oguz, and if there was a sponsor beyond that, Your
24 Honor, it wasn't 3M, but I couldn't answer that beyond that.

25 MAGISTRATE JUDGE NOEL: Okay.

1 THE COURT: And that was published in what?

2 MR. BLACKWELL: In the *Journal of Clinical*
3 *Anesthesia*, Your Honors, and the Oguz study. And but again,
4 this is really underscoring the overarching point that if
5 the plaintiffs are going to talk about particles, they
6 should in the same breath talk about the study of particles
7 from the Bair Hugger that found bacteria that could be
8 colonized, and since there's been a study of this many times
9 then where is the proof and if relies only on ipse dixit,
10 then surely there must be some found, and in the real world
11 there haven't been any.

12 THE COURT: Okay. Were the medical experts --
13 plaintiffs' medical experts asked about this study or did
14 the study come out after they were -- what did the
15 plaintiffs' experts -- what did Samet -- do you call him
16 Samet or Samet?

17 MR. BLACKWELL: Samet, Your Honor.

18 THE COURT: And what did SJS have to say about
19 this study, if anything?

20 MR. BLACKWELL: If I may have just a moment, Your
21 Honor, just to --

22 (Counsel conferred.)

23 MR. BLACKWELL: So Your Honor, I did, as you can
24 see, conferred with my colleague, Mr. Gordon, who talked to
25 them and that -- and said that the study was addressed and

1 discussed and the experts simply said it didn't change their
2 opinions with respect to the Bair Hugger causing surgical
3 infections. And if -- and the plaintiffs will perhaps
4 better speak to it, but our recollection is from the
5 depositions they were asked about it, and they said it
6 didn't change their opinions in the case.

7 THE COURT: Bear with me, I'm about to ask a
8 question I might not -- I'm just formulating. It might not
9 make sense. But I'm thinking about any potential difference
10 between Minnesota's Frye-Mack standard and the Daubert
11 standard, and it strikes me that --

12 MR. BLACKWELL: Oguz.

13 THE COURT: Oguz might be a statement of what is
14 generally accepted now because it's a kind of close to a
15 gold standard, purports to be kind of -- and I'm not
16 familiar with this thing at all so all I know is what I just
17 see here. Maybe it was in the materials and I just didn't
18 get to it, but can you just talk about from a legal
19 standpoint any differences between Daubert and Frye-Mack in
20 terms of what is the appropriate use of a study like this or
21 also the I guess that would also include the 2013, 400
22 experts from around the world meeting in I'm sure a very
23 nice place.

24 MR. BLACKWELL: What does Frye-Mack under
25 Minnesota Rule 702 or Daubert under 702, I think the

1 conclusion is they essentially merge with respect to Oguz.
2 This is a biological plausibility study and as such, it
3 isn't viewed as a gold standard study because it's not even
4 epidemiology and it's not a clinical trial. So establishing
5 only biological plausibility still leaves a gap to show that
6 that biological plausibility will turn into causing
7 infection in fact.

8 THE COURT: I see.

9 MR. BLACKWELL: So what we see here from Oguz and
10 the organization of the prosthetic surgeons, etc., the
11 international consensus is that it is not generally accepted
12 in the scientific and medical community that the Bair Hugger
13 causes -- it's not accepted that it causes surgical
14 infections.

15 Now, under Minnesota Frye-Mack, that more or less
16 should end the inquiry. It is not generally accepted.
17 Under Daubert and in 702, it is simply a factor in the
18 analysis that the Court should consider.

19 MAGISTRATE JUDGE NOEL: Just as a -- not to put
20 too fine a point on it, but as a legal matter it's possible
21 that Judge Leary may come to one conclusion under Minnesota
22 law and Judge Ericksen come to a different conclusion under
23 federal law. That's a possibility in light of the way this
24 has been teed up. Is that a correct statement?

25 MR. BLACKWELL: Your Honor, that is a possibility,

1 though obviously we wish you wouldn't.

2 MAGISTRATE JUDGE NOEL: You don't see it.

3 MR. BLACKWELL: Right, Your Honor. I get that
4 because the inquiry under Frye-Mack is really somewhat of a
5 subset analysis from the one the Court may consider in
6 Daubert. We think on the facts of this case they would be
7 the same to the extent that Daubert allows for the
8 consideration of other factors, those other factors relate
9 to there being other reputable science, scientifically valid
10 proof of causation. And when you look at what they in fact
11 have as scientifically valid proof of causation, they only
12 have theoretical studies. They have a CFD. They have
13 reliance on McGovern. And beyond that they have just a lot
14 of lawyer argument and accusations about what 3M didn't do
15 and so that somehow helps them meet their burden to show
16 what they in fact did do. And I think based on -- the
17 difference to me is abstract and theoretical, but on the
18 actual facts of this I think they come out in the same place
19 because there's no there, there. The science here, to some
20 extent, is like a Potemkin village. There's nothing behind
21 it.

22 So continuing on, and so here with Oguz, we see
23 the conclusion that Oguz and from the nine published studies
24 over the past 25 years put here under the heading of what's
25 generally accepted in the scientific community. What's

1 generally accepted is, is that there is no evidence that
2 particles coming out of the Bair Hugger result in the
3 creation or formation of bacteria. If the plaintiffs want
4 to get up and talk about particles, the only relevant
5 question is what study do you have of a particle that was
6 able to colonize bacteria from the Bair Hugger and hasn't it
7 been studied? And then where's your study if it's to the
8 contrary? And Bradfrod Hill doesn't get you there because
9 we only reach Bradford Hill after there's been the proper
10 positive association finding, according to the *Reference*
11 *Manual on Scientific Evidence*.

12 So as I said here, when I talk about -- this is
13 just a couple of cases on the whole issue of biological
14 plausibility, Your Honors, and *In Re Zoloft* where this came
15 up, where this says plaintiffs potentially admissible
16 supports no more than an association between Zoloft and
17 certain birth defects, causation may be based on mere
18 possibility. *In Re Accutane*, it flat out says, biological
19 plausibility is not proof of causation. And then *Bausch &*
20 *Lomb*, the suggestion of biological plausibility is
21 insufficient to demonstrate causation. The same points that
22 biological plausibility is in of and by itself is not
23 sufficient.

24 So I want to switch gears for a minute and point
25 to the exploratory studies and what --

1 THE COURT: What --

2 MR. BLACKWELL: I'm sorry, Your Honor.

3 THE COURT: We're going have to take a break. It
4 doesn't have to be right this second, but we've been going
5 since about nine clock and it's approaching 11 so.

6 MR. BLACKWELL: This is a good point, Your Honor,
7 to take a break.

8 THE COURT: When you said "I'm going to switch
9 gears," what I heard was break time. All right. So we'll
10 -- you want to know exactly how long, ten or so minutes. We
11 won't come out until somebody comes and makes sure that
12 you're all back in your places.

13 MR. BLACKWELL: Ten minutes is plenty for us, Your
14 Honor.

15 THE COURT: Okay. All right we're in recess.
16 Many.

17 (Recess taken from 10:45 a.m. until 11:07 a.m.)

18 THE COURT: Please be seated. We're back in
19 session. And I'll just let you know in advance that Judge
20 Noel is going to have to leave at around 11:30. He's got
21 criminal duty, and I offered to let him take somebody into
22 custody if that's what it is, so whoever is talking at that
23 point, don't take it -- or do take it personally. I'm just
24 telling you the facts.

25 MR. BLACKWELL: Thank you, Your Honor.

1 THE COURT: Mr. Blackwell.

2 MR. BLACKWELL: When we left off before the break
3 I had started to talk about the so-called exploratory
4 studies. What's important, first and foremost, to note
5 about these studies is that the date of them. They all are
6 relatively recent. The vast majority of them postdate even
7 all of the biological plausibility studies I showed Your
8 Honor. And certainly they postdate by quite a few years the
9 first clinical trial in 1991. And I point those dates out
10 for reasons that will become apparent in just a little bit
11 as to why these studies were created, why do particle
12 studies, airborne studies, bubble studies in the face of all
13 of these biological plausibility studies that have already
14 been done that had turned out negative, so why not first
15 establish biological plausibility since that is obviously a
16 huge scientific question if it's to be believed that the
17 Bair Hugger causes surgical site infections but instead turn
18 around and start doing these theoretical exploratory studies
19 in response?

20 And we'll show Your Honors momentarily these were
21 done primarily to get results that could be used for
22 marketing purposes and not for purposes of proving actual
23 causation in fact of an infection caused by Bair Hugger is
24 the main thing. But in any event all of these studies,
25 which were part of the plaintiffs' reliant studies in

1 McGovern as a kind of bubbles and component to it, none of
2 them conclude that they established a causation between the
3 Bair Hugger and an infection.

4 So as Your Honors have seen this before, all of
5 them ultimately conclude that no causation, we showed this
6 at science day, so this is plaintiffs' science. And one the
7 of things that's extraordinary about this case is that the
8 plaintiffs are advancing the theory that the Bair Hugger
9 causes surgical or prosthetic joint infections, and the very
10 studies that they have relied upon disclaim causation.

11 So I wanted to, and I won't dwell on the FDA
12 letter, I talked about it before in the opening, but there's
13 one aspect of it that I did not show Your Honors where the
14 FDA says what it looked at, before it sent this letter dated
15 August 30, 2017, and here it says to determine if there's an
16 increased risk of surgical site infections when forced air
17 thermal regulating systems are used during surgery, the FDA
18 collected and analyzed data available to date from several
19 sources, including medical device records received by the
20 agency, information from manufacturers and hospitals,
21 publicly available medical literature, operating room
22 guidelines, and ventilation requirements. It's a broad
23 enough search that they undertook, and they said that after
24 a thorough review of available data, the FDA has been unable
25 to identify a consistently reported association between the

1 use of forced air thermal regulating systems and surgical
2 site infections and they recommended the continued use of
3 thermal regulating devices, including forced air thermal
4 regulating devices for surgical procedures when clinically
5 warranted.

6 So I want to stop with that segment and now speak
7 with Your Honors. I'm sorry, Judge Noel.

8 MAGISTRATE JUDGE NOEL: I was going to say, do
9 they give any guidance anywhere as to what, quote,
10 clinically warranted means? When is it clinically
11 warranted? When is it not clinically warranted?

12 MR. BLACKWELL: They don't in the letter itself.
13 And it's physician obviously determination, but given the
14 body of science that exists for all of the benefits of
15 patient warming from, you name it, from reduced surgery site
16 infections to fewer adverse health consequences of surgeries
17 in general, it is now the standard for patient care. And
18 you won't see very many studies of the sort that existed in
19 the early 1990's because it is so accepted that patient
20 warming is the standard now that you wouldn't have a
21 comparison group of somebody not being warmed compared to
22 someone who is, but the FDA doesn't specify, clarify in its
23 letter.

24 I wanted to take a moment to show that in fact in
25 the general scientific and medical community that the

1 plaintiffs' theories being espoused here are in fact
2 rejected in the community.

3 And if I could, just to tee this up, Your Honor, I
4 have a graphic that I'll go through very quickly because
5 this may be just a big note version of scientific medical
6 causation. So we have on the far left the experimental,
7 which is theoretical, that's the bubbles and the particles
8 and so on which can never be sufficient proof of actual
9 causation because they don't prove that anything causes
10 infection in the real world alone. The biological
11 plausibility studies, which we looked at, those that don't
12 establish causation in fact. Valid epidemiology can
13 establish at least a positive association to which there may
14 be applied Bradford Hill factors if there's a valid
15 epidemiology to do it.

16 And what is ideal, and this is in the middle is
17 the sort of chasm, the analytical gap or leap between these
18 types of evidence on the left and actually valid proof of
19 causation, scientifically valid proof of causation, the
20 *Glastetter* standard on the right side, and the chasm in the
21 middle is the abyss into which scientifically invalid proof
22 of causation, you know, plunges.

23 THE COURT: Are those waves?

24 MR. BLACKWELL: Those are waves, Your Honor. No
25 fish and sharks but definitely waves. So if I may, I'm just

1 going to pull this all up at once just to show which things
2 fall under which. The plaintiffs have particles, bubbles,
3 and CFD, that's way on the left, for experiment also slash
4 theoretical. Biological plausibility are studies that
5 actually test whether the Bair Hugger is releasing bacteria
6 in the OR or increasing the quantity of bacteria in the OR.
7 There's not that. And epi, there's various types of
8 epidemiology studies. And simple argument is they don't
9 have to have epidemiology, it is not really -- shouldn't be
10 tantamount to an argument they don't have to have anything
11 or that we could simply have particles and bubbles.

12 And obviously we talked about gold standard, gold
13 standard types of epidemiology and clinical trials before,
14 but the point here is that the plaintiffs are relying on the
15 particles and the bubble studies and the litigation CFD
16 created in litigation, and they're relying on McGovern. And
17 McGovern, we will take a deep dive on that, but McGovern
18 disclaims a causal basis for any positive association. They
19 don't have epidemiology, they don't have any biological
20 plausibility studies, they don't have any gold standard
21 proof of causation, and so that leaves us talking about
22 particles and bubbles, et cetera.

23 And so that's where we are. I wanted to tee this
24 up because there may be other arguments that Your Honors
25 hear where we'll we point out which box we're talking in at

1 a given time when we're talking about the evidence. I'm
2 going to -- going through this, we just talked about
3 international consensus standard just before the break where
4 this particular body came down on sort of rejecting the
5 claim, at least saying that there is not science there that
6 shows an increase in SSI's related to the use of forced-air
7 warming devices, but then there are a number of other
8 independent reviews that find there's no link between
9 forced-air warming and surgical site infection.

10 And I wanted to review a few of those with Your
11 Honors, and the first being, Your Honors, from ECRI, and
12 ECRI is a very respected I call it a pure science
13 organization. They -- it's nonprofit. They follow
14 evidence-based medicine. They provide support to and for
15 some several thousand entities, including state and federal
16 governments in and in governments even outside of the United
17 States, amongst others.

18 And as you can see here, ECRI had been made aware
19 of the allegations in this lawsuit, contamination by
20 forced-air warming in April of 2013. And ECRI undertook
21 review of the literature. They learned in March 2013 about
22 the complaints filed here. They have reviewed the
23 plaintiffs' petition. It doesn't present any new
24 information that would alter the conclusions we have drawn
25 in this article. And what they in fact conclude is that

1 there's insufficient evidence to establish that the use of
2 forced-air warming systems leads to an increase in surgical
3 site infections compared to other warming methods.

4 And I wouldn't stop at ECRI because we also have
5 the *Journal of Bone and Joint Surgery*, which, again, is a
6 peer review journal in the field of orthopedic surgery, and
7 here they find in December 2014, Thus the literature appears
8 to indicate that forced-air warming can impact laminar flow
9 under certain very specific conditions but any actual
10 clinical impact on surgical site infections must be
11 considered unproven at this time. So the stuff that --
12 distributing air flow and so on, does it clinically result
13 in an increase in surgical infections, again, looking at the
14 Bair Hugger, they said the science wasn't there.

15 AORN, which is the Association of Perioperative
16 Nurses, and they represent some 41,000 RAM's across the
17 country, in October of 2013 looked at the issue also, and
18 they said our review uncovered no conclusive evidence that
19 the use of forced-air warming increases the risk of surgical
20 site infections. The evidence also doesn't support the
21 concern that use of forced-air warming may cause an increase
22 in bacteria near or on the patient or cause unwanted air
23 flow disturbances.

24 So I'm showing this to Your Honors to give you
25 some sense of what the scientific medical community is in

1 fact saying. This isn't a neutral issue. They are
2 addressing the issue. They are rejecting the issue. And
3 quite generally. In fact, if there is a reputable health or
4 patient organization that's come out in favor of the theory
5 that plaintiffs espouse, they will point to it when they
6 stand up here. We're not aware of any.

7 THE COURT: Could I ask about the AORN journal? I
8 think the plaintiffs in their papers refer to that as an
9 article by a nurse, is that -- what is that article, the
10 AORN journal? It says "we." Was there a study or something
11 done, or was that --

12 MR. BLACKWELL: Simply review of literature.

13 THE COURT: By a nurse or by?

14 MR. BLACKWELL: Can you see there?

15 THE COURT: Who did it?

16 MR. BLACKWELL: Yeah, let me find out who did it.
17 They're saying a Ph.D., professor of nursing did it, so it
18 was a professor of nursing. That's a Ph.D., professor of
19 nursing.

20 THE COURT: Okay.

21 MR. BLACKWELL: But certainly an independent
22 review, and they're to be reviewed and reacted to, but it's
23 consistent with everything else that's out there, including
24 studies that in fact specifically looked at McGovern, the
25 idea that McGovern stands for the proposition that the Bair

1 Hugger is causing infections.

2 Dual Infection Control Outreach Network, DICON,
3 looked at this issue and now in analyzing McGovern, and this
4 is how McGovern is viewed in the general scientific
5 community. Not adequate power, not properly controlled, not
6 statistically significant. No adequate power, properly
7 controlled, statistically significant, reproducible study
8 has been published demonstrating an increased risk of SSI
9 due to the used of forced-air warming, and that was the
10 reaction to McGovern is that it is not such a study in part
11 because of the improper controls.

12 And back to the *Journal of Bone and Joint Surgery*,
13 this medical journal, peer review medical journal, in the
14 field of orthopedic surgery will recognize McGovern failed
15 to account for age or medical comorbidities, failed to
16 account for other infection control measures implemented
17 during study period, and co-author was employee of
18 conductive warming company was the criticism from the
19 *Journal of Bone and Joint Surgery*.

20 ECRI again weighed on McGovern, and ECRI found the
21 study lacked documentation of normothermia during surgery.
22 Two types of warming were not applied concurrently. The
23 data was collected retrospectively and noted the changes in
24 antibiotics and thromboprophylactic regimens which was the
25 antibiotic and the blood clotting regimens that changed in

1 between the two test periods between the HotDog and the Bair
2 Hugger.

3 The FDA weighed in on this issue too because
4 Dr. Augustine was apparently making claims drawing from the
5 McGovern study, and it came to the attention of the FDA, and
6 the FDA wrote to him and that's what this letter is,
7 December of 2012, where the FDA says, "The evidence provided
8 in support of such clinical claims does not satisfy the
9 requirement for a pre-market submission for a cleared
10 intended use for the HotDog patient warming system or
11 provide conclusive evidence of a causal relationship between
12 the use of forced-air warming and higher infection rates,
13 nor does it demonstrate a clinically relevant comparison
14 between the use of the HotDog system and forced-air warming
15 in general or the HotDog system in particular. Prospective,
16 well controlled, well designed studies are needed to provide
17 the evidence needed to support a reduced infection rate
18 claim and a comparative claim." This is all a part of the
19 FDA's efforts to ask Dr. Augustine to stop making those
20 kinds of claims.

21 THE COURT: Is this a warning letter that's
22 referred to in the first line there?

23 MR. BLACKWELL: Yes, yes. They issued a prior
24 warning letter to Dr. Augustine, and he was supposed to have
25 taken actions to have complied with it. Now they're

1 reviewing kind of what he had done in response to the
2 warning letter and found that they had not gone far enough.
3 And then he said to the extent he's touting McGovern as even
4 a clinically relevant comparison, it's not even that, and if
5 a proper study was to be done, the last sentence highlighted
6 there is what type of study would needed to have been done
7 which McGovern was not.

8 So stopping there, Your Honor, I showed Your Honor
9 this before about what type of observational study would do,
10 if we talked about studies that were rejected, what type of
11 science would suffice? Proper observational studies would
12 suffice, proper epidemiological studies would obviously
13 suffice, clinical trials would suffice, none of which exist,
14 none of which do we have here. Biological plausibility
15 doesn't, but they don't have that here, and exploratory
16 studies certainly don't.

17 So one other point here on observational studies
18 as it relates to confounders is the second bullet point that
19 I put here for Your Honors to see from the *Reference Manual*
20 *on Scientific Evidence* that what the association found in a
21 observational study, it must hold, even when effects of
22 confounding variables are taken into account by appropriate
23 methods; for example, comparing smaller groups that are
24 relatively homogenous with respect to the confounders. And
25 that is fatal to using McGovern in ways that transcends its

1 bounds given its limitation and the fact that it did not
2 address the issue of confounders.

3 There must be a plausible explanation for the
4 effect of the independent variable. Alternative
5 explanations in terms of confounding should be less
6 plausible than the proposed causal link. So all of this is
7 from the *Reference Manual on Scientific Evidence* for what's
8 a proper observational study.

9 So when we talk about the types of evidence,
10 here's a quote from *Glassteter* and the types of evidence
11 that the plaintiffs proffered there. Here they talk about
12 the particle studies, arguments from lawyers, et cetera,
13 corporate statements. "Viewed in isolation, Glassteter's
14 different pieces of scientific evidence do not substantiate
15 our experts' conclusion that Parlodel can cause
16 intercerebral hemophage, strokes. Likewise, we do not
17 believe that the aggregate of this evidence presents a
18 stronger scientific basis for Glassteter's supposition that
19 Polydol can cause these strokes." And that -- and so this,
20 putting all the evidence together, saying this isn't just an
21 individual piece but we'll put it all together.

22 And in the *In Re Lipitor* case is even more to the
23 point. "To be sure, it's possible for the entirety of the
24 evidence to support an opinion even when individual pieces
25 of evidence are not sufficient in isolation, but it's also

1 possible that multiple piece of insufficient evidence add up
2 to insufficient evidence."

3 And so we saw the quote earlier from *Bausch &*
4 *Lomb*, I won't repeat it.

5 So I told Your Honors that I wanted to turn your
6 attention to the manipulations of sorts that are behind the
7 particle, the exploratory studies and how they came about
8 that the plaintiffs are relying upon. And that's the
9 segment I'll spend a few minutes showing Your Honors at this
10 point. And first, we know a bit about the
11 Augustine-Albrecht connection, but as Your Honors can see
12 here, it goes beyond just knowing each other. They have a
13 promissory note relationship that is an addendum to the
14 first promissory note dated September 27, 2007, and in
15 August 2010 between Albrecht and Augustine, but here's the
16 real kind of punch line to this. And I'll pull this --

17 THE COURT: I suppose I could look, but how long
18 did the relationship between Albrecht and Augustine, when
19 did that conclude, if ever?

20 MR. BLACKWELL: I don't know that it's concluded
21 to this day. Do we know if it's concluded?

22 (Counsel conferred.)

23 MR. BLACKWELL: Pardon. Mr. Goss said that
24 Albrecht testified that to this day he doesn't know for sure
25 if he still owes Augustine money on this note, so they may

1 still be in some form of relationship, but certainly through
2 all of the McGovern period and the studies at issue here
3 they were in relationship.

4 THE COURT: Because some of his I guess he only
5 put that disclaimer in the one study, it's not in the other
6 one, so it's not that he didn't have the relationship
7 anymore?

8 MR. BLACKWELL: Yes, that's correct. And even
9 more to the point here, it isn't just that Albrecht would
10 have stood the financial benefit. What this is pointing at
11 here is that if he didn't agree to a certain number of
12 studies for Dr. Augustine, he would have to pay back \$21,000
13 currently owed within 60 days of the term to stop work, and
14 some of those studies, the three you see, some here in the
15 A, B and C are studies that are in the plaintiffs' reliant
16 studies materials for their particle stuff, but there's a
17 real connection there.

18 But I had drawn Your Honors' attention to some of
19 the dates on the biological plausibility studies, and we
20 look at the dates on the exploratory studies, and here's
21 Scott Augustine writing to Mike Reed, one of the study
22 authors. And here he's saying, this is talking about doing
23 these particle studies, these bubble studies in the face of
24 there being biological plausibility studies out there, and
25 he says, Scott Augustine, I like this plan of doing the

1 studies because we know the outcomes before we do the
2 studies and yet they are scientifically and clinically
3 important questions that need verification in multiple
4 studies. I should mention that when we repeated the
5 experiment of tracer smoke, et cetera.

6 And so the point here is that this is the very
7 opposite of the scientific method that's being employed
8 because they don't start with the scientific question and
9 follow it blindly to its conclusion; they start with the
10 conclusion and then turn around and look for a path to it.

11 And here that's the very opposite of what you
12 should do. And Dr. Fogel *In Re Accutane* did the same thing,
13 showing a bias of wanting to reach a conclusion which is not
14 right. So what that makes clear is why not do biological
15 plausibility? He says, I'm personally not too excited about
16 culturing the wound at the end of the case, even directly by
17 irrigation where you get bacteria then. This is a crap
18 shoot that could go either way.

19 I think it's important to consider that even if
20 this type of study were to turn out positive, it could be
21 considered to simply -- to simply be another intermediate
22 step similar to particle detection over the wound. In other
23 words, and this is the real punch line about these
24 exploratory studies that Dr. Augustine is behind, it does
25 not conclusively answer the question does forced-air warming

1 cause wound infections? Therefore, I'm not sure that it
2 really adds enough to our case to take the risk of a
3 negative study to get to the real scientific question. And
4 so the real kind of punch words here is these exploratory
5 studies are intermediate steps. They even referred to the
6 particle detection as an intermediate step and intermediate
7 in the sense that they don't answer the question does
8 forced-air warming cause a wound infection?

9 So it would have been very simple, again, to use
10 an agar plate to test whether there is any biological
11 plausibility, do any particles associated with the Bair
12 Hugger contain bacteria? Real easy to test, agar plate.
13 And so the fact is, years before they did these exploratory
14 studies from what Mark Albrecht calls the Augustine
15 Publication Factory --

16 THE COURT: You look for a really good picture of
17 him to put up there?

18 MR. BLACKWELL: That is one, Your Honor, there you
19 go. You should see him in the morning. And so I'm not sure
20 where they came from actually.

21 So 2007, 2008, this is a few years before they did
22 these bubble and particle studies, they had actually gone to
23 a hospital in St. Cloud and Alexandria and Northfield and
24 Hastings to try to measure airborne bacteria to gather
25 whether any particles from the Bair Hugger actually contain

1 any bacteria, and they found no differences in Bair Hugger
2 count -- I'm sorry, bacteria count with the Bair Hugger on
3 or off and no bacteria in the air coming out of even the
4 Bair Hugger hose.

5 So in 2009, McGovern and Reed simulate surgeries
6 to analyze whether use of Bair Hugger could increase
7 bacteria around the operative field. Not particles, actual
8 bacteria. The experiment showed no notable increase in
9 either the ambient particle count or bacterial count in the
10 vicinity of an operative field when a forced-air warming
11 device was used in the normal intraoperative manner.

12 Legg study in 2010, tried to identify if there was
13 any increased bacterial level associated with the Bair
14 Hugger by using a slit sampler at the surgical site.
15 Results, all samples came back with less than one CFU,
16 colony-forming unit, the same level his hospital required
17 for operating room air. So no different than background.

18 So this was already known about actually trying to
19 find bacteria for particles before they decided to do these
20 exploratory particle smoke and bubble studies from the
21 so-called Augustine Publication Factory, as Mark Albrecht
22 referred to it.

23 So here is the plaintiffs' science and how it
24 translates into the studies that Dr. Augustine and Mark
25 Albrecht that were behind, as Your Honor can see, no

1 causation involved, bubbles, particles, particles, bubbles,
2 temperature difference, particles, particles, bubbles, and
3 particles. And what Your Honor knows about these studies
4 already is every one of them came back finding no causation
5 ultimately.

6 So enough on that, Your Honor. I'm going to now
7 talk about the McGovern study as the study that Dr. Samet
8 pointed to as the only one that shows an association in the
9 real world which is what we're concerned about here. And as
10 Your Honors have noted before, this -- I think there was a
11 statement made before about the study authors standing by
12 their opinions from before. Here is Mark Albrecht who's one
13 of the study authors who's talking about Scott Augustine
14 making claims from McGovern study, and he says this is one
15 of those things where we are step close to the line and we do
16 have important information to present that clinicians should
17 be aware of but we also have to be careful that we do not
18 state claims regarding proof of infection reduction.
19 Unfortunately, Scott Augustine likes to say that he's
20 convinced of such a relationship even though I tell him it
21 is unsupported and I do not agree. Unsupported and I do not
22 agree. And he says, well, that is the difference between
23 research and marketing.

24 That is what the author, Mark Albrecht, says that
25 any claims about infection reduction, which is what the

1 McGovern study purports to show, he has told Scott Augustine
2 that such claims are unsupported and that he doesn't agree
3 with those types of claims.

4 Again, there is no question that once the
5 confounders are controlled for, and I just put here the
6 quote from Albrecht's deposition and that where he says he
7 didn't even need to run an analysis to know that there
8 wouldn't be any statistically significant difference if the
9 anticlotting drug and the antibiotics were controlled for.
10 And, again, that fact I think is not in dispute.

11 So with that, Your Honor, I will stop, and I want
12 then now to take the dive into the McGovern data which
13 Mr. Gordon will speak to, and I'll sit down.

14 THE COURT: Thank you, Mr. Gordon.

15 MR. COREY GORDON: May I please the Court,
16 counsel. Good morning, Your Honors.

17 THE COURT: Good morning. Did you want to sit or
18 are you okay standing?

19 MR. GORDON: I am okay standing.

20 THE COURT: Because the podium will accommodate
21 the chair too.

22 MR. GORDON: I appreciate that, Your Honor. If
23 that changes, but hopefully I won't be up on my feet long
24 enough that that will be an issue. And if I am,
25 Mr. Blackwell will give me the hook. Mr. Blackwell said

1 that I would be plumbing the depths and getting into the
2 weeds here, so I guess that makes me either a plumber or a
3 weedwhacker, and my wife will tell you those are two skills
4 I clearly do not have.

5 And I want to talk about -- and my goal here is to
6 go deep, do a deep dive on the two so-called epidemiological
7 studies that have surfaced in this case, the Augustine 2017
8 study and the McGovern 2011 study. And the reason I want to
9 start with Augustine even though it's later in time is some
10 information we learned about it fairly recently. It's a
11 very recent study and therefore, there is some information
12 that I think we have that's pretty useful to the Court.

13 Judge Noel had asked about, you know, where have I
14 heard this before, essentially? And indeed he did. He got
15 a prelude when we moved to enlarge the discovery time so we
16 could take some discovery from hospitals. So he -- actually
17 he's not missing -- he's not missing that much because he
18 did get a little preview of this, but we did get some
19 additional information from the hospitals that supposedly
20 provided the data upon which Augustine's paper was based.

21 But why is the Augustine paper important at all?
22 Well, number one -- I was born in the 50's. Technology
23 ain't my thing either. Plaintiffs' counsel at that motion
24 to compel was saying no, no we don't need -- because our
25 experts aren't going to rely on it. Unfortunately, or for

1 better or for worse, Dr. Samet made it clear that he is
2 considering the Augustine paper as supporting proof, you
3 know. I asked him -- he volunteered it. Why, you know, how
4 can you transfer this one study McGovern from one hospital
5 in England back to the United State? And he said, well,
6 it's useful.

7 But now there's a second report, that's from the
8 United States hospitals, it has essentially a very similar
9 quantitative assessment of the risk. And, you know, I asked
10 him, did the Augustine paper have any impact on your
11 opinion? Yeah, I regarded the paper as another piece of
12 observational evidence that provides an estimate risk to
13 deep joint infections associated with the Bair Hugger
14 device.

15 So whatever plaintiffs' counsel want to say about
16 it, I don't know how an expert unrings the bell. And to the
17 extent that might even theoretically be possible, we haven't
18 seen any supplemental report from Samet saying I got
19 religion, I'm no longer relying on the Augustine paper. And
20 I'm not exactly sure what the basis would be for saying he
21 doesn't rely on it because the very indicia of reliability
22 that he says allows him to rely on McGovern are present in
23 the Augustine paper, indeed in some respects, they're on the
24 surface there, even stronger. It's a peer-reviewed study.
25 It's a -- and in the case of Augustine, it's a multicenter

1 study of three different reporting studies that have some
2 strength ordinarily in epidemiology.

3
4 It reports an even higher odds ratio. It's got
5 more subjects. On its surface, all the factors that
6 Dr. Samet says yep, I can rely on that, Augustine has it in
7 spades, yet now they want to --- even though Samet says I've
8 been relying on it, they want to turn away from it.

9 It also provides a lot of insight as to how Dr.
10 Samet, Dr. Jarvis, Dr. Stonnington, all the -- every one of
11 the experts who rely on McGovern, how they go about their
12 reliance materials. To use that Potemkin village analogy, I
13 mean, those fans of 18th Century Russian history would know
14 that Captain Greg used to float down the rivers and see
15 those Potemkin villages along the river and think, oh, this
16 is great, you know, my country is wonderful. They are
17 moving down the river a little bit and they were
18 continuously fooled. This is science. And Dr. Samet, Dr.
19 Jarvis, and Dr. Stonnington were fooled. They like what's
20 pretty on the surface and they don't dig below the surface.

21 And I think it's very useful for us to take a
22 little bit of a deep dive below the surface because what
23 lurks there is very illustrative and informative. And I'm
24 going to borrow a quote from Mr. Ciresi, I wrote it down, I
25 liked it, I'm going to enter into my pantheon, epidemiology

1 has been so misused. Let's see how misused. This is the
2 Augustine 2017 paper where he says I'm going to compare Bair
3 Hugger to air-free HotDogs, and here's kind of a quick
4 summary of what his methodology. In the papers, hips and
5 knees, and he used a one-year baseline for Bair Hugger,
6 followed by a 60-day washout period when they switch over to
7 HotDog, we're not going to collect data for 60 days because
8 we can't tell which -- where the infection was going to come
9 from, but then the 6 to 24 months of HotDog, those are the
10 infection data we're going to compare to, important
11 background for what he's doing.

12 This, again, would be what the peer reviewers
13 would have had before them. So he says only hospitals
14 reporting no other significant changes, so he's saying don't
15 worry, no confounders, we've already taken care of that. He
16 says we have a paid independent statistician performing
17 statistical calculations. Guess who? Mark Albrecht. Paid
18 in the sense that he had the sort of damacles of the
19 promissory notes hanging over his head. This study was a
20 small letter C on that promissory note that Mr. Blackwell
21 just showed the Courts.

22 He says the only independent variable, kind of
23 backward way of saying no confounders, the only independent
24 variable is the warming. And the most common brand, just
25 lest there be any doubt, he's saying Bair Hugger was used by

1 all three hospitals. Okay. He doesn't identify the
2 hospitals in this. We know what they are, A, from earlier
3 drafts of this that were produced in discovery; and B, from
4 this testimony of deposition. First one is Ridgeview
5 Medical Center in Minnesota. The second one is the
6 Orthopedic and Sports Institute, Fox Valley, I just
7 shortened it to Fox Valley in Wisconsin, and the third one
8 is South Nassau Community Hospitals in New York.

9 And I want to start with South Nassau. They
10 responded to our subpoena. Their director of anesthesia
11 provided an affidavit, and the first thing he said was we
12 never use the Bair Hugger. Yeah, they were using a
13 different forced air warming device, a Stryker warm air, but
14 part of why he was shall we say nonplussed when he saw this
15 study even though South Nassau wasn't identified in the
16 paper, when he found out that that was the case he was not
17 particularly happy. He didn't provide any knee data.
18 Remember he said -- Augustine said it's going to be hip and
19 knee data. He didn't provide any just -- and was in
20 response to one of Augustine's sons who just asked him for
21 some data. Not only were there not any changes, he said
22 during this time period we were doing multiple things to
23 decrease the infection rate.

24 So and I spared you the deep dive on the actual
25 data because I wanted to just focus in on the data from

1 Ridgeview. This is how the data are presented in the
2 Augustine paper. Again, this is what the peer reviewers
3 would have seen. They would have seen that Augustine is
4 claiming that in that two-year period of HotDog use there
5 were two infections out of a total of 677 procedures. The
6 way Albrecht does his statistical stuff is he disaggregates
7 it. He did it in McGovern. He does it here. I
8 reaggregated it just so you can see the numbers. Two out of
9 the 677 in the HotDog and the forced air, that would be Bair
10 Hugger, and that should be the 12 months immediately
11 preceding the switchover but for the 60-day washout, six
12 Bair Hugger infections out of 388, hip and knee, remember
13 that.

14 Here are the actual data that Ridgeview provided.
15 There's to remind us of the two out of 677 and six out of
16 388. Where do these come from? Well, first of all, the six
17 out of 388 come from 2006 knees only. The switchover
18 occurred at the end of 2007, beginning of 2008, so what
19 Augustine did was for his one-year baseline, he picked 2006
20 for knees, skipped over hips, skipped over the year 2007.
21 For HotDog, he selected, again, just knees, 332 plus 345,
22 667, there's your two out of 677, so this is what he's
23 reporting. Had he followed his protocol with these data, he
24 would have, first of all, he would have reported combined
25 hip and knee, the one-year baseline of Bair Hugger would

1 have been 2007 and it would have reported 2 out of 537 or an
2 infection rate of .37, and he would have reported 6 out of
3 1007 HotDog procedures, total or infection rate of .60.

4 Now, using Augustinian analysis or
5 Augustinian-Albrechtian analysis, that translates to a
6 62 percent increase from Bair Hugger to HotDog, meaning that
7 you're well more than twice as much at risk if you have a
8 HotDog then if you have a Bair Hugger. These numbers are as
9 completely preposterous and as meaningless as taking the
10 numbers that they manipulated in McGovern and as he
11 obviously manipulated here to say that there's a big
12 difference between Bair Hugger and HotDog in favor of
13 HotDog.

14 The point here with this, and I'm sparing Your
15 Honors the deep dive from the data on the other ones as
16 well, this whole thing is cooked. It's completely
17 fraudulent. The idea that Scott Augustine did an objective
18 study and he followed his protocol and he gathered these
19 data and he presented them made it look like there was a
20 78 percent reduction when you switch from HotDog to Bair
21 Hugger, it is a complete fraud, an unmitigated lie.

22 And as noted, who did the statistical analysis
23 under his direction? Mark Albrecht. This brings us now --

24 JUDGE LEARY: Can you tell us anything about the
25 journal in which this article was published?

1 MR. COREY GORDON: Yes, it's an online journal out
2 of Italy, *Page Press* has a series of publications that they
3 pay 500 euros, 600 euros to publish in.

4 JUDGE LEARY: The author -- the organization that
5 wishes to publish the article pays the money to have it
6 published?

7 MR. COREY GORDON: That's right. There's been a
8 proliferation with the Internet of online journals, and
9 there's a -- they run the gamut of respectability to not so
10 much.

11 JUDGE LEARY: But would it be fair to say that
12 this journal is a journal of self-published articles?

13 MR. COREY GORDON: It is essentially.

14 JUDGE LEARY: Is there any review of the
15 scientific validity?

16 MR. COREY GORDON: They say it's subject to peer
17 review. There's an unusual twist in that when you submit
18 your paper for publication, you are required by their rules
19 to provide them with the names of two potential reviewers.
20 Sometimes a lot of journals ask for suggestions. They
21 require them, but they say it's peer reviewed. There's an
22 editorial board.

23 This is an important point, if I may, Your Honor,
24 peer reviewers can only review what is presented to them and
25 have to rely on the integrity of those who are submitting

1 them. There has been an explosion of peer-reviewed
2 published literature being retracted after it was uncovered
3 that there were problems with it. And this is not just
4 online journals, although online journals tend to be
5 disproportionate. Some of the top journals in medicine are
6 plagued with this as well. One might attribute it to the
7 pressures of --

8 JUDGE LEARY: I'm not really that interested in
9 the --

10 MR. COREY GORDON: I apologize.

11 JUDGE LEARY: -- general situation with regard to
12 self publication. I'm concerned about the scientific
13 reliability of the journal in which this article was
14 published. And if you don't know, that's --

15 MR. COREY GORDON: Well, I do. It has an impact
16 factor that tends to be between about two and three, which
17 means it's not in the junky of journals, it's not in the top
18 tier of journals. It's probably closer to the junky but
19 wouldn't it characterize it as the journal -- I'm not
20 faulting the journal. I understand they are looking now at
21 this information, and I would hope that they would --

22 JUDGE LEARY: You've answered the question, thank
23 you.

24 THE COURT: Does the article itself reveal the
25 skipping over of the 2007 -- what you just pointed out the

1 knee, you know, you've got the '06 knee and then nothing
2 from '07 and then --

3 MR. COREY GORDON: Not at all.

4 THE COURT: So that wouldn't be evident from the
5 face of the journal?

6 MR. COREY GORDON: That's correct, Your Honor.
7 And that's the point, that on the face of it, you know, if
8 you look at that chart, wow, that looks pretty compelling.
9 You know, you've got three different places, they all show a
10 reduction when they switch from Bair Hugger to HotDog. You
11 combine the totals, you've got an odds ratio of 4.28,
12 conference interval of 1.5 to 12.9 and a P value of 0.0022,
13 it's all fake.

14 THE COURT: So you're telling us all this. Is
15 there a witness who says something similar? Is there a
16 witness who says it's not consistent with respectable
17 scientific methods to rely on a study like this and I -- is
18 there a witness?

19 MR. GORDON: Yes, two witnesses actually. There's
20 Professor Borak who, frankly, was the one to kind of unravel
21 this, at least with respect to Ridgeview, and so testified
22 in his deposition, but Dr. Samet, when we showed him at
23 least some of this, he hadn't seen it before. And I sort of
24 my final question was, doctor, if this is true, would this
25 concern you? Would this trouble you? And he said yes, it

1 would.

2 THE COURT: Did he talk at all about whether in
3 his non-litigation work, he would rely on a study like this?

4 MR. COREY GORDON: Well, I'm going to answer that
5 question slightly differently. We did address how in his
6 published work he has talked about the need to rely, to
7 have, you know, more than one epidemiological study, to have
8 consistency, to show consistency across multiple studies,
9 you know, similar to the reference manual quote that
10 Mr. Blackwell put up. And he acknowledged that that's what
11 he's written and that he stands by that. And, you know, I
12 was asking him then how do you -- basically how do you just
13 rely on McGovern? Well, he relies on McGovern because
14 that's what was presented to him. I guess that's -- and
15 that goes right to really it's the heart of the Daubert
16 issue, you know, how does he do that? How does he look at
17 one on its face --

18 THE COURT: He said he also relied on McGovern
19 with others, including this --

20 MR. COREY GORDON: Well, but the only
21 quantification of risk he acknowledged in the real world,
22 those are his words, was McGovern, then a little later on
23 bolstered by this, but you take away McGovern and Augustine
24 and there is no quantification. It's all theory. It's all
25 plausibility. You've got smoke and you've got bubbles.

1 THE COURT: Right. So he specifically relies on
2 McGovern for the quantification, so the statement of how
3 much the Bair Hugger increases the risk, but Daubert
4 wouldn't require a finding of a certain quantification, so
5 to the extent the quantification relies solely on McGovern,
6 that doesn't get you where your motion wants you to go, does
7 it, because it's the ability to do it, the ability to cause
8 the infection at all, not --

9 MR. COREY GORDON: I think I understand what Your
10 Honor is asking, and I think the answer is if there is some
11 valid evidence of increased risk, the inability to put a
12 specific number on what that increase is becomes a factor to
13 consider.

14 THE COURT: That was my question.

15 MR. GORDON: Here, what he is saying, I asked him
16 because in his opinion he said the Bair Hugger is a
17 substantial contributing factor. I said so, you know
18 without the quantification, can you still say it's a
19 substantial contributing? No, I can't. Can you say it's
20 insubstantial contributing factor? No, he couldn't. The
21 point being whether it does in fact increase risk at all is
22 gone.

23 THE COURT: I see.

24 MR. COREY GORDON: But, certainly, yes, the need
25 to be precise in quantifying it is relaxed, I guess, if

1 you've got something that shows it really does increase
2 risk, but without McGovern and Augustine, they have
3 absolutely nothing to show that it really does increase the
4 risk. They've got theory. And in the face of that theory,
5 there's a lot of solid evidence that their theory is wrong,
6 but all they have to even get them to that point where you
7 could invoke the Bradford Hill factors or whatever else they
8 want to talk about, you got to have something to show
9 there's a positive association. And the main horse they
10 rode was McGovern. When Augustine came along out of the
11 calvary, the calvary has arrived, the problem with the
12 calvary, let's ignore that.

13 But now if I may, I'd like to do a little bit
14 deeper dive, peel back the curtains, if you will, on
15 McGovern. There's a lot on the surface of the McGovern
16 paper that we will talk about as to why it, on its face, is
17 unreliable, on its face should raise some red flags to
18 Dr. Samet and anyone else who's trying to rely on it, but
19 through discovery, we've learned a lot more about it. One
20 of the things we got at the very end of our transatlantic
21 sojourns when Dr. McGovern voluntarily appeared for his
22 deposition was that he gave us his -- all of his electronic
23 files on this study. Thousands of pages. And we weren't
24 able to get that from any of the other English authors
25 because they were all -- they were only appearing pursuant

1 to the order of the English High Court which, under their
2 interpretation of English law, precluded us from compelling
3 document production. We got their deposition, but they
4 weren't required to produce underlying data or anything else
5 related to the actual task, but Dr. McGovern gave us his
6 whole file, electronically, and said that that's what it
7 was.

8 And one of the things that was very interesting
9 was there was an initial draft of the McGovern paper appears
10 as -- it's designated manuscript read 1 PDF, I'm calling it
11 McGovern draft 1, and the main things I want to point out
12 was when they were drafting this version of it, they started
13 out by saying that they're going to do a two-year study
14 period from 9/1/2008 to 9/1/2010. And I just draw Your
15 Honor's attention to the fact that 9/1/2008 is the way we
16 Americans write dates; it's not the way the Brits write
17 dates. They would have written 1/9/2008 or if they were
18 trying to do September, they would go 1/9/2008 -- or 1/9 --
19 1 September. So the point being that it's clear this is
20 Albrecht.

21 But the main thing I want to I call your attention
22 to in this one is their initial draft of Figure 7. Figure 7
23 looms large in this case. It's a version of Figure 7
24 ultimately is published. And indeed, in response to our
25 pointing out that the plaintiffs have previously represented

1 to the Court that Dr. Samet had reviewed all of the
2 underlying broad data of McGovern, their response was, well,
3 no, no, he reviewed Figure 7 as it was published.

4 Well, this is Figure 7 as it was initially
5 drafted, and the two things I want to point out, number one,
6 is again the start date is September 2008; number two, the
7 way the line is depicted here is that it's not a flat line.
8 It shows down and then up and that there's a clearly a very
9 obvious hump where a peak of infections just before the
10 switch over to HotDog. That peak of infection just happens
11 to coincide with the seven months that they were using
12 rivaroxaban and had such disastrous consequences with it
13 that they switched back to the anticlotting drug they were
14 using prior to that. But anyone -- so anyone looking at
15 this as it is drafted had it been published this way,
16 presumably could have at least scratched their head and
17 said, gee, you know, the infection rates weren't constant
18 over the Bair Hugger timeframe, they, you know, three
19 percent down to two percent, then over a very short period
20 of time skyrocketed to four percent, what's going on here?
21 If it's the Bair Hugger, why wouldn't -- you know, why would
22 there be these peaks and valleys, particularly this huge
23 peak just before the switchover?

24 Well, they apparently thought well of that because
25 in a very next draft, that line gets flattened out, but I

1 want to jump now to --

2 THE COURT: Just leave that up for a second.

3 MR. COREY GORDON: Sure. You'll see it again.

4 THE COURT: So the dates are different, so the
5 Figure 7 as published has July of '08, January of '09, July
6 of '09, January of '10, and then we skip over, so it skips
7 that hump period, right?

8 MR. COREY GORDON: Well, no, the hump period is
9 included in -- in what they analyze as being the Bair Hugger
10 cohort. The graphic depiction of that hump disappears and
11 the scrunching, if you will, of the -- what they call the
12 jitter plot at the top, I don't know if your eyes are good
13 enough to discern the difference, but you can see that
14 there's a little bit of -- a cluster of infections at the
15 top and a sparsity in the middle of the Bair Hugger period,
16 but there's no way to quantify --

17 THE COURT: Oh, it's above the infection rate
18 grid?

19 MR. COREY GORDON: Correct. On the left-hand axis
20 is the percentage. The bottom is a combination of the
21 timeline and that massive cluster of what looks like ink
22 smears, supposedly the number of cases, the number of
23 procedures, and then the dots at the top reflect the
24 infections.

25 THE COURT: I see.

1 MR. COREY GORDON: And I'm going to take a little
2 bit deeper dive on that in just a second. And part of what
3 was going on here, it's clear from the text, and I spared
4 you that but it is in our materials, you can see from the
5 text at the time they were writing this they had only 171
6 Bair Hugger procedures, meaning they had about three months
7 of data, meaning September -- they were basically up to
8 September. And at that point, there were no reported
9 HotDog, infections so, you know, you can't really do a very
10 valid comparison of some number of infections to zero. So
11 they were waiting to see if they had any infections in the
12 HotDog period before they could do a comparison, and that
13 came about by the end of December they had enough, they had
14 seven months of HotDog data and they had some infections so
15 now they had some numbers to report.

16 Let's see how they drafted that the version have,
17 what I would call the penultimate version, McGovern draft
18 10. And this is, you will see from the numbers, that this
19 is now based on the data that the final publication is based
20 on. It just has that Augustinian magic applied to it. This
21 is before the Augustinian magic has been applied. Okay. In
22 draft 10 they show there are 372 HotDog procedures versus
23 1,065 Bair Hugger procedures. I know this is pretty meaty,
24 and I apologize.

25 THE COURT: We can follow you so far.

1 MR. COREY GORDON: Following me one thing is.
2 Staying awake is perhaps a bigger challenge. But at this
3 point they are reporting a percentage of infections in the
4 HotDog period in that 372 group as 1.08. Back calculate
5 that, that translates to four infections. The 3.1 over
6 1065, it's a little more ambiguous depending on how you
7 round up, it could 31, it could 32, it could be 33, so that
8 spells out the numbers for the Bair Hugger.

9 Now let's look at their Figure 7 as drafted in
10 this penultimate version. You'll see that they -- as Your
11 Honor pointed out in the final version, they moved that --
12 the start date back to July of 2008, and I'll give you I
13 think a good explanation as to why that happened. But the
14 key thing I want to point out here is in this scatterplot at
15 the top in the HotDog only period are four infections, four
16 dots. And you can see they flattened out the infection line
17 so, you know, anybody looking at this would not be alerted
18 to the fact that, hmmm, there was quite a peak there right
19 before they switched.

20 And just for comparison, I'm going to go back and
21 forth a little bit here. So we have these four infections.
22 Now, to unravel this a little bit and see what was going on
23 at the old --

24 JUDGE LEARY: Just for clarification, Mr. Gordon,
25 are you saying that with regard to this draft 10, the flat

1 line, that's really misrepresenting the data?

2 MR. COREY GORDON: Well, it represents it in the
3 sense that it's just an average. It's --

4 JUDGE LEARY: So it's not plotted in terms of the
5 rate of infection at different points in time?

6 MR. COREY GORDON: Correct.

7 JUDGE LEARY: All that's been done with regard do
8 draft 10 is to take the information and then average it
9 across the length of time that the Bair Hugger was used?

10 MR. COREY GORDON: That's exactly right.

11 THE COURT: So why would you need it represented
12 as a rate over time if it's just an average?

13 MR. COREY GORDON: Well, I mean, you wouldn't, but
14 if the average -- I mean, you know, how do with statistics,
15 the average of something that varies dramatically can appear
16 to be pretty static, but when you have something that varies
17 dramatically, it suggests that there's something going on
18 here.

19 THE COURT: I mean, how do you plot -- I don't
20 know, maybe you're not the right person to ask this, but how
21 do you put on a grid for July of '08 and then your vertical
22 axis says "infection rate percentage" and what you plot
23 there is an average for things that haven't happened yet?

24 MR. COREY GORDON: Your Honor, I must agree with
25 you. I am not the right person to ask, and to the extent

1 you're asking me to --

2 THE COURT: I just don't know -- all right.

3 MR. COREY GORDON: I think that's pretty slimy
4 because just looking at that, it looks like, well, there's
5 been about three, a little over three percent infection rate
6 across 20 months.

7 THE COURT: Right.

8 MR. COREY GORDON: And that's not the case.

9 JUDGE LEARY: Would it be fair to say that the
10 average that's represented on draft 10 for the Bair Hugger,
11 the average infection rate would be less if you pulled out
12 the spike in infection rates that might have been
13 attributable to a change in regimen, antibiotics regimen?

14 MR. COREY GORDON: Absolutely.

15 JUDGE LEARY: Is that what you think happened?

16 MR. COREY GORDON: Absolutely. And in about four
17 slides I'll show that.

18 THE COURT: Okay. Go ahead with your --

19 MR. COREY GORDON: To further -- I just want the
20 Court to have a better understanding of what's going on
21 behind the scenes here. Mark Albrecht gets the data that he
22 uses to come up with draft 10 and Figure 7. This is his
23 e-mail that he sends to his colleagues after he's done his
24 preliminary analysis of the data. This is an e-mail
25 January 31, 2011. The e-mail goes to Mike Reed, to Paul

1 McGovern, and it also goes to Scott Augustine, pretty much
2 everything goes to Scott Augustine, and Professor Nachtsheim
3 gets cc'd on it. And he says at the top, Barely made it
4 with those sample numbers. Attached is an updated chart of
5 infection data. The difference is significant based upon
6 the results of logistic regression. Some highlights. There
7 have been 3.1 for forced air, N equals 1065 and 1.08 for
8 HotDog equals, N equals 372. And boy, they're doing their
9 happy dance. Okay. Hopefully we made it here to
10 significant difference so I'll update the manuscript to
11 reflect the new infection numbers.

12 Kind of an interesting way to do a study, to keep
13 gathering data until you make it to statistic significance.
14 Boy, you got to cross your goal line and you do your -- I
15 dont know, you do duck duck gray duck or for those of you
16 from out of Minnesota duck duck goose. And duck duck gray
17 duck is correct.

18 How does it get published? What happens? Well,
19 this goes to Scott Augustine, right? And we've already seen
20 what Scott Augustine thinks of the truth and the importance
21 of adhering to scientific integrity. And just barely making
22 it to statistical significance, just below P and having --
23 and they've already calculated the odds ratio using -- they
24 didn't in that draft, but if you -- the odds ratio of 3.1 to
25 1.08 percent would be about 2.87. And, you know, okay, the

1 confidence interval would be very wide and right about one
2 but just barely significant.

3 Call me a skeptic, but this goes to Augustine and
4 Augustine maybe thinks, hmm, you know what, it's good we
5 show a positive association but it's not as strong as it
6 could be. Is there a way we can just make it a little
7 stronger?

8 Here's the published version. Remember that 1065?
9 It becomes 1066. Remember that 372? It becomes 371.
10 Remember the -- this time they specify the number of
11 infections for Bair Hugger. This is interesting, they say
12 32 -- this is in the published paper, and they say that's
13 3.1 percent. No matter how many times you calculate it, 32
14 is three percent of 1066 which makes me wonder what the peer
15 reviewers were doing, but that's really a very minor issue
16 compared to the decrease in HotDog infections from four to
17 three.

18 So here you have the comparison, the penultimate
19 version, they sent it -- he sent it to Scott Augustine, we
20 barely made it, 1065 versus 362 -- 372. On the 1.08
21 percent, we need four infections in HotDog. Published
22 version, there's only three infections in the HotDog period,
23 371 versus 1066. So how did that happen? How do those four
24 infections become three infections in the HotDog period?
25 Well, we think we have the answer. Dr. McGovern in his

1 voluminous materials provided us with an Excel spreadsheet.
2 And we'll talk about this when we talk more about the
3 Holford -- Dr. Holford's analysis and data upon which he did
4 that analysis. But Dr. McGovern had the spreadsheet that
5 showed all the infections, the dates, the age, the sex, the
6 procedure for just the infections. It was an Excel
7 spreadsheet that called out just infection as opposed to the
8 master file, if you will, that had all the procedures, all
9 1400 or so procedures.

10 And what he did was -- you have to squint at this,
11 we did a callout here, somebody, unlike the master set of
12 data that had all those bits of information, including the
13 infection data and the type of infection, there's one column
14 that's added that isn't in that master set and that's a
15 column that shows whether the codes as either become CFW,
16 that's HotDog, or FAW, that's Bair Hugger. And you can see
17 that the four dates that are shown here are 9/1, 9/15,
18 10/18, and 11/22. Those are all in the Bair Hugger period.
19 In fact, they're well within the Bair Hugger period. The
20 switchover occurred from March, April, and May, so it's
21 completed by the end of May. From June 2010 on, they were
22 using just HotDog. So September is well in the middle of --
23 in fact, it's dead in the middle of the HotDog only period.
24 Yet for some reason, September 15th, 2010, right in the
25 middle of the HotDog only period, this one procedure gets

1 coded as being a Bair Hugger procedure. So what happens?

2 Well, and by the way, I just wanted to point out
3 that the -- all the data on McGovern 16 corresponds exactly
4 to the master set of data upon which Dr. Holford did his
5 analysis with the one exception of the 9/15/2010 having a
6 Bair Hugger coding. All of the other data are still there,
7 the British convention 15-9-2010, the age, the sex, the type
8 of procedure, the type of bacteria, all that is identical.
9 It's not different because there is no warmer coding on the
10 master data. On this document, it gets coded as FAW. So
11 how does that impact things? Well, those four that appeared
12 in the penultimate draft, they become three. What happens?
13 Well, one of them in the middle gets coded as FAW.

14 Now, one could say -- I suppose one could say when
15 then reviewed the data, oh, gee, I don't know how this
16 happened, but for some reason out of all of those 372
17 procedures that we did when we were supposedly only using
18 HotDog doing, for some reason on September 15, 2010, someone
19 just decided, well, let's use a Bair Hugger on this one case
20 and that one just happened to end up in an infection. Maybe
21 that's possible. But if that's the case, you would expect a
22 footnote, okay, here's a fourth dot on this scatterplot,
23 footnote, you know, for whatever reason, this one procedure
24 was done.

25 You would also expect there would be at least some

1 e-mail back and forth. And I'm going to anticipate what
2 might be a question is what do the witnesses have to say
3 about this? Unfortunately, when we got these documents from
4 Dr. McGovern, we had already deposed Albrecht, we had
5 already deposed Reed. We didn't have -- weren't able to ask
6 them. Dr. McGovern, even though his name is on the
7 beginning of this, is the first name on the study, he had
8 already left the hospital. He was in his early stages of
9 his residency. He left the hospital before the switchover
10 even occurred. He was involved in the bubbles but he had
11 nothing to do with, other than there's kind of a repository
12 for all the e-mails back and forth, for the final aspect of
13 epidemiological lead, interrupted time series, observational
14 study. So I asked him why would there be a Bair Hugger
15 procedure in the middle of September? I mean, well, yeah.
16 And he said, which all he could say, of course, is I don't
17 know.

18 So what's the impact of this? Moving one or
19 re-coding one, moving back the start date, we didn't talk
20 that much about that, but I want to show that. Remember
21 they started out they were going to start in September of
22 2018 -- or 2008, and by the time they did this, they had
23 bumped back two months. Well, okay, two months, more data,
24 that's good, isn't it? Well, what happens is, and this is
25 from Dr. Holford's chart -- or his expert report. He did a

1 month-by-month analysis of what would be the statistical
2 significance of any odds ratio depending on which month you
3 started the study, the red line being, if you will, the
4 statistical significance goal line.

5 THE COURT: Who did this?

6 MR. COREY: I'm sorry?

7 THE COURT: Who did this?

8 MR. COREY GORDON: Professor Holford. He's our
9 biostatistical expert. And what he showed -- and by the
10 way, he used a chi-square for this analysis. If you're
11 lucky, you won't hear any more about it, but I'm afraid
12 you're going to hear more about a chi-square.

13 THE COURT: Well, the plaintiffs are going to say
14 it's a different -- the use of a chi-squared makes it kind
15 of an apples-to-oranges comparison.

16 MR. COREY GORDON: Yeah, that's basically what
17 they're going to say, and I'm going to keep you in suspense
18 to our response because it's close to lunch and I don't want
19 to put you to sleep. But the point is was a chi-square
20 analysis, and what he -- what he showed was kind of
21 interesting. If you start in September of 2008, you don't
22 cross the statistical significance goal line, but if you
23 start in July of 2008, you make it barely across the goal
24 line. So the start date is so sensitive in this study that
25 just moving it back two months moves it from not

1 statistically significant to statistically significant. By
2 the way, moving it forward a month or moving it back more
3 than two months would obliterate statistical significance.
4 Moving forward one month for the first six or seven months
5 is still below significance. The sweet spot that they have
6 to use in order to achieve statistical significance was a
7 start date of July 1, 2008, and to gild the lily, they added
8 an additional -- they moved a HotDog to the Bair Hugger.

9 Now, maybe they switched --

10 THE COURT: Let's just briefly -- and since Judge
11 Noel is not here, I'll say the 15 words -- or what'd he,
12 25 words or less, tell me why this is an admissibility, all
13 of this -- let's say this is all true, tell me why that's an
14 admissibility issue rather than a weight issue?

15 MR. COREY GORDON: That's -- obliterating this
16 little one right there, it's certainly weight versus
17 admissibility. Mr. Ciresi said, oh, this study has. You
18 know, confounders. That's true in an abstract sense, but at
19 some point a study becomes so fraught with problems, it's
20 just, it collapses. The whole point of the gatekeeping
21 function, if you will, or even Frye-Mack is, you know, is
22 there, there? Is there something reliable upon which the
23 experts can offer an opinion?

24 THE COURT: And --

25 MR. COREY GORDON: And the start alone is not --

1 the moving the one infection, that's not it. The
2 confounders --

3 THE COURT: What is the legal standard for when it
4 drops below the -- when it becomes a matter of
5 admissibility?

6 MR. GORDON: Well, there are a number of cases,
7 for example, that say the opposite. There's no bright line
8 in terms of, for example, statistical significance. You
9 could have something that's statistically significant that
10 doesn't isn't -- that doesn't, you know, punch your ticket
11 and you get past the gate. Conversely, there are cases that
12 stand for the proposition that if you don't have, you know,
13 statistical significance, that is necessarily fatal. So
14 it's not -- there is a certain totality of the evidence.
15 But, again, at some point, when you've got multiple
16 confounders, when you've got multiple flaws in the
17 methodology, when you've got disclosed confounders that were
18 not considered, known/unknowns we might want to call them,
19 when you've got undisclosed confounders, not considered, and
20 you've got pretty strong evidence of data miscoding, to be
21 charitable, manipulation to be more of an advocate, at some
22 point the data simply -- the study is not reliable because
23 the data have not been properly analyzed and properly
24 presented.

25 THE COURT: So it affects the preponderance that

1 is normally used in evaluating factual underpinnings of an
2 admissibility determination so it goes to whether there is
3 -- the plaintiffs can show by a preponderance of the
4 evidence that this would be reliable?

5 MR. COREY GORDON: I would guess that it's a
6 preponderance standard, but, you know, in our main -- most
7 -- you know, at least most cases I'm familiar with, the
8 science doesn't -- isn't fraught with this kind of
9 underlying fraud and manipulation. And in this district, I
10 think the closest parallel would be the *In Re Viagra* MDL
11 where the Court originally permitted the expert testimony to
12 go forward based on a peer-reviewed study that had been done
13 by the proffered expert but then discovery revealed a lot of
14 problems with the underlying data and in revisiting that --
15 the initial decision, the Court in that case excluded it.

16 THE COURT: All right. Thank you.

17 MR. COREY GORDON: I know it's 12:20 and I've got
18 a choice which means you've got a choice.

19 THE COURT: How many more minutes do you have?

20 MR. COREY GORDON: Well, what I was going to say
21 is the next stuff is about the confounders I can just as
22 easily do that in the Holford/Borak defense. It's entirely
23 up to you.

24 THE COURT: What's the thumbnail of what you're
25 going to say about the confounders? Are you going to talk

1 about the anticlotting?

2 MR. COREY GORDON: Yep.

3 THE COURT: You're not going to talk about the
4 obesity component?

5 MR. GORDON: Oh, yes. Let me do the obesity just
6 before we go lunch, if I may.

7 By the way, before I started working on the Bair
8 Hugger case I was 40 pounds lighted, so I'm going to say
9 there's a positive association between working on this case
10 and my now being obese.

11 THE COURT: You were four pounds lighter?

12 MR. COREY GORDON: Yeah. Well, I did have 2 foot
13 -- feet -- foot surgeries in between and, I don't know, that
14 may have had something to do with it, but that's just the
15 confounder.

16 So back to McGovern, what do they say, they say
17 not unfortunately, but there are two unfortunatelies in
18 here, and this is the unfortunately about the antibiotics
19 and the thromboprophylaxis. And I'm going to skip over that
20 for a second to the second unfortunately. Unfortunately,
21 the record keeping was a complete -- this is what we would
22 call the patient-specific factors, blood transfusion,
23 obesity, incontinence, and fitness for surgery. Which have
24 been identified elsewhere as important predictors for deep
25 infection. That's an important sentence because plaintiffs

1 and their experts want to say, well, before you have to
2 think about confounders, you have -- first, there has to,
3 you know, a priori determination that they have -- that they
4 could be a confounder.

5 Well, we have some disagreement over the details,
6 but there's no disagreement that the authors of the study
7 were saying, hey, these were identified as important
8 predictors for deep infections, i.e., potential confounders,
9 but they don't have any information. These are known
10 unknowns. So were the Bair Hugger, would the Bair Hugger
11 cohort a whole bunch more obese, incontinent, you know,
12 people who needed blood transfusions? The biggest issue
13 really is probably.

14 We don't know, but fitness for surgery and the
15 idea that fitness for surgery could be a really important
16 factor that you have to consider, you don't have to take my
17 word for it. Take Dr. Jarvis's word for it. When Dr.
18 Jarvis was at the -- that's one of plaintiffs' expert. When
19 he was at the CDC, they were called into a hospital in
20 Tennessee to investigate an apparent problem with a cluster
21 of infections in their knee surgery. And going in, they had
22 the suspicion that it was one particular surgeon.

23 THE COURT: And he says we don't want to disagree
24 so he went to the Nth degree, blah, blah, blah.

25 MR. COREY GORDON: They did a great job in

1 analyzing all potential factors, and when they did it, they
2 found, yeah, the surgeon was statistically -- it was
3 associated as statistically significant but so was fitness
4 for surgery. This surgeon, for whatever reason, had a whole
5 bunch more people with what's called ASA scores, they were
6 high ASA scores compared to all of the other surgeons, so to
7 compare apples to apples, you had to factor that in.
8 McGovern didn't do that. And they say that we didn't do
9 that. And, you know, for that reason, just on that alone.

10 One more slide because I promised Judge Leary that
11 I would get to this and I'm finally going to get to it.
12 When you slice out the change in antibiotics and the change
13 in anticlotting drug, there was a period in between where
14 they were the same for Bair Hugger as they were in HotDog.
15 In other words, they switched the antibiotics earlier then
16 switched the anticlotting drug and then switched back. So
17 by the time they got to the HotDog period, they were using a
18 protocol that they had actually used in the middle, remember
19 that graph that we saw on the earlier graph, Figure 7, when
20 you slice it like that, there is no difference, zero
21 difference in the infection rate.

22 Don't believe me. Believe Mark Albrecht who when
23 we forced him to kind of go through this analysis conceded,
24 yeah, that would not be, there would be no significance. In
25 fact, he didn't need to run an analysis to know that it was

1 not significant.

2 THE COURT: How much infections were there in that
3 seven-month period?

4 MR. COREY GORDON: The seven-month period of the
5 HotDog either three or four, I believe there were three -- I
6 think there were three in the five-month period. I can -- I
7 like to be precise so, I mean, I'll -- I don't know if we
8 have that on a chart, so I can certainly provide that to the
9 Court after lunch.

10 THE COURT: Okay.

11 MR. COREY GORDON: But just, the point is, just
12 these two factors alone, if they had controlled for them,
13 there's no there, there. There's no difference. And this
14 also underscores just the huge impact that the anticlotting
15 drug when, and we get to Holford and Borak we'll talk a lot
16 more about that, but unless the Court has any questions, I
17 think I can actually end there.

18 JUDGE LEARY: I'm good.

19 THE COURT: So when we come back from lunch,
20 what's going to happen?

21 Thank you, Mr. Gordon.

22 MR. COREY GORDON: Thank you, Your Honor.

23 MR. BLACKWELL: Your Honor, we will close before
24 lunch with our arguments on the exclusion of SJS, and then
25 as to whether the plaintiffs want to take them one by one,

1 I'm presuming --

2 THE COURT: I guess to be more specific about my
3 question, are you about done with SJS?

4 MR. BLACKWELL: Yes, Your Honor. I have only one
5 other thing to put up.

6 THE COURT: Okay. Well, why don't you put that
7 up, and then we'll -- welcome back.

8 You know how I said before you shouldn't, I think
9 you should. So why don't you do whatever you're going to
10 do.

11 MR. BLACKWELL: Just this in closing, I put up the
12 final quote from *Glastetter* that I think speaks, to some
13 extent, the types of evidence the plaintiffs need here in
14 support of the plaintiffs' medical causation claim.
15 Although plaintiffs' chain of medical reasoning appears
16 sound, its major premise remains proven. *Glastetter's*
17 experts failed to produce scientifically convincing evidence
18 that Parlodel causes vascular constriction. Her experts
19 relied on various types of scientific data, published case
20 reports, medical treatises, human re- challenge data, even
21 animal studies, internal company documents, and the FDA's
22 revocation of parlodel's indication for suppressing
23 lactation to establish that parlodel acts as a vacular
24 constriction. We agree with the district court's conclusion
25 that this data does not demonstrate to an acceptable degree

1 of medical certainty that parlodel can cause intercerebral
2 hemorrhage, stroke.

3 The types of evidence, the data, that the
4 plaintiffs have here in this case is even less than the
5 *Glastetter* court had. At least they had animal studies.
6 They in fact had the revocation from the FDA as opposed to,
7 in this case, the endorsement of the product by the FDA, at
8 least the endorsement of the continued use of the product.

9 So we'll rest on our papers with respect to the
10 rest. Our view is that the general state of the knowledge
11 in the scientific and medical community is that the theory
12 espoused by the plaintiffs here is generally rejected; that
13 the experts' opinions are based upon flawed data; or in the
14 case of exploratory studies and CFD, items that don't tend
15 to prove causation and weren't intended to and the
16 methodology is flawed. Thank you, Your Honor.

17 THE COURT: Thank you, Mr. Blackwell.

18 JUDGE LEARY: What do the parties intend to do
19 with regard to any visual slides that they present today or
20 during these hearings?

21 MR. BLACKWELL: We had thought, Your Honors, to at
22 the end of each day look at the ones we actually used and
23 then to put those together for the Court on the following
24 day. We haven't discussed it with the plaintiffs yet, but
25 to make them available to the Court and of course the

1 opposing party then too.

2 MS. CONLIN: We're fine with that. I mean, I did
3 bring a slide deck on my presentation, but perhaps it makes
4 sense to provide them to the Court at the close or tomorrow
5 morning.

6 THE COURT: Then you've got the advantage of
7 knowing which ones were actually used.

8 MS. CONLIN: That's true.

9 MR. BLACKWELL: Thank you, Your Honor.

10 THE COURT: Thank you. We'll resume at 1:15.
11 We're in recess.

12 (12:30 p.m.)

13 (Lunch recess.)

14
15 (1:18 p.m.)

16 (IN OPEN COURT)

17 THE COURT: Please be seated. Mr. Ciresi.

18 MR. CIRESI: Yes, Your Honor. I was just waiting
19 for the judges to sit.

20 THE COURT: Ms. Conlin.

21 MS. CONLIN: Good afternoon, Your Honors. I'd
22 like to start with the Court's question about the FDA letter
23 this morning and the point that that FDA letter, and we
24 don't know what information the FDA had when it put that
25 letter out, but we do know that it says where intraoperative

1 warming is warranted, in cases which intraoperative warming
2 is warranted, and this is a document, an Arizant document,
3 that came from 3M's file, dated June 23rd of 2007.

4 And it's regarding the Bear Paws product, and the
5 Bear Paws product is a forced air warming device
6 manufactured and sold by 3M that warms a patient up and
7 blows hot air on them before surgery. So Bear Paws is
8 typically used before surgery, Bair Hugger during surgery.
9 And if you look at the advantages listed there for using the
10 Bear Paws, warming up the patient before surgery, it says,
11 Can be used when intraoperative warming is contra-indicated,
12 and then in parentheses it says, Aortic cross clamp in
13 orthopedic cases.

14 And that's what we're talking about here is
15 orthopedic cases and the environment of use, and you heard a
16 little bit from Mr. Ciresi, and you're going to hear more
17 about it as we go through that the reason why orthopedic
18 surgeries are contra-indicated for a Bair Hugger device is
19 because it only takes one or two microbes, CFUs, to land on
20 that implant to cause an infection, and it distinguishes it,
21 and their experts do, too.

22 By the way there is no dispute between the
23 experts. There is a difference between a surgical site
24 infection and what's known as a deep joint infection or
25 prosthetic joint infection, and that's because, as

1 Mr. Ciresi alluded to, you can have infections that are
2 caused post surgery, on the top of the skin or in the
3 tissue, from bad bandaging or, you know, being unclean or
4 shower. You name it.

5 But that's the issue, and this document from 2007
6 says, Reduces the potential for nosocomial transmission of
7 pathogens by eliminating the need for intraoperative
8 warming. I'm quite certain that the FDA did not have that
9 document.

10 The other that I just want to show you because it
11 goes to this FDA letter and one of the questions this
12 morning on particles versus bacteria, this a document from
13 Michelle Hulse Stevens, and you heard 3M talk this morning
14 about the Orthopedic International Consensus, and they put
15 up slides from that.

16 And this is actually an internal memo from
17 Michelle Hulse Stevens, head of 3M Infectious Disease
18 Division. She's in charge of all this, reporting back on
19 what she heard at that meeting. She says, All, I sat in on
20 the group addressing the OR environment for this consensus
21 document. There is an amazing concern about any
22 particulates in the air during joint replacement surgery and
23 almost uniform comment that forced air warming increases
24 particulates in the air.

25 So then they go on in the last line, They equate

1 particulates with bacteria in the air and cite studies. Do
2 not have the citations. She didn't have the citations that
3 support this. That's some of the evidence that I'm going to
4 talk with you about today.

5 *Daubert*, as this Court is aware, basically allows
6 for the liberal admission of expert testimony. It only need
7 be relevant and reliable, and I don't think as we go through
8 this with respect to our three experts you're going to see
9 much dispute about the reliability of the methodology that
10 they employed in arriving at their conclusions.

11 And under the Frye standard under state law,
12 there's an additional prong which is, it has to be accepted
13 if it's novel, and this isn't a case in which the
14 methodologies that the scientists are employing are novel.
15 3M doesn't even dispute the methodology employed by our
16 experts. What they're disagreeing with is the conclusion.
17 I think Mr. Gordon made that pretty clear right before
18 lunch.

19 Eighth Circuit does follow *Daubert's* liberal
20 approach. Doubts are resolved. Excuse me. There's a typo
21 there -- in favor of admissibility. Factual basis for the
22 expert opinion goes to credibility not admissibility, and a
23 District Court abuses its discretion if it results in doubt
24 in favor of excluding expert testimony or decides the
25 correctness of an expert's opinion.

1 I want to talk with you at the start a little bit
2 about the way the briefing took place in this, and I am
3 loathe to cast aspersions on colleagues, particularly those
4 in Minnesota, but I do want to point out a couple of issues
5 in connection with the briefs that were submitted.

6 One of the things that they say, and this is in,
7 the top one is in their first brief on page 14, the very
8 first point under their argument section. The McGovern
9 study is the only epidemiological study cited by Samet,
10 Jarvis and Stonnington in their report, and it goes on in
11 their reply brief says, Here by contrast, McGovern is the
12 only observational study that SJS rely upon for their
13 opinions.

14 In other words, the story that has been told is
15 that the experts in this case are relying on McGovern and
16 McGovern alone, and that is simply not true. Let me show
17 you. Dr. Samet, he is our epidemiology expert in this case.
18 He is world renowned. When he was working for us in this
19 case, he was at U.S.C. He is now a dean in Colorado at a
20 public health facility, but he was also head of epidemiology
21 for Johns Hopkins for a couple of decades.

22 He used the Bradford Hill criteria to evaluate
23 causation in this case. Defendants don't dispute that he
24 used the wrong methodology. They in fact endorsed
25 Dr. Samet's methodology, and you'll hear when we get to

1 Dr. Borak, 3M's expert, he employed the same methodology,
2 and there was a lot of talk this morning on, well, McGovern
3 and these other things don't show causation, and causation
4 is never shown in an observational study.

5 What an observational study shows is association,
6 and that's what McGovern showed was an association between
7 use of the Bair Hugger and deep joint infections. Causation
8 is what an epidemiologist does when they look at all of the
9 evidence that's been amassed in a case, and they make a
10 scientific judgment as to causation, and that's what
11 Dr. Samet did here.

12 Dr. Samet, contrary to the suggestion in 3M's
13 brief that we are riding the McGovern train and the McGovern
14 train alone, he considered multiple lines of evidence. If
15 you look at his reference list in connection with his expert
16 report, he looked at hundreds of medical articles. He
17 looked at the deposition transcripts of a number of the key
18 players, including all of the McGovern authors who were
19 deposed.

20 There were a couple that refused to in England. I
21 think Dr. Harper was one of them, but for everybody that was
22 deposed, he looked at those. He looked at a number of
23 internal 3M documents and Arizant documents. He looked at
24 depositions of 3M employees. He looked at the medical
25 literature, and he looked at the expert reports.

1 So to suggest that there's a single McGovern train
2 that we're riding is just simply not borne out by what the
3 experts actually did. Dr. Jarvis, you'll recall, Your
4 Honor, Your Honor saw him at science day. He was head of
5 the CDC Division of Infectious Diseases for 17 years.

6 Again, like Dr. Samet, 3M doesn't dispute his
7 qualifications, and like Dr. Samet, he employed a multi
8 disciplinary experience of investigating infectious
9 outbreaks, just as he did at the CDC, and he cited dozens of
10 sources, along with McGovern, and if you look at his report,
11 you'll see, for example, on pages 9, 10, 11, 12, I mean the
12 citations to the relevant evidence that he as a scientist
13 relied upon in reaching his judgment of causation in this
14 case is not limited to McGovern as suggested.

15 Now, defendants may disagree to its conclusions,
16 but that's an issue for the jury, as we talked about this
17 morning. Dr. Stonnington, he approached this case from a
18 clinician's standpoint. He performs a high number of
19 surgeries in the orthopedic area, the area of interest, and
20 since he started looking into it, he stopped using the Bair
21 Hugger altogether.

22 Again, looking at evidence from a clinician's
23 standpoint, his investigation and assessment is something
24 that is well accepted and allowed under Minnesota law and
25 the *Daubert* standard.

1 Now, I want to talk with the Court a little bit
2 about the mechanisms of causation, and this is actually a
3 figure from Dr. Samet's report. It's Figure 3, and it's the
4 mechanism by which Dr. Samet concluded that the Bair Hugger
5 increases the risk for deep joint infections.

6 You have the Bair Hugger device, and as you know
7 from science day and some of the other hearings, that's a
8 device that typically sits on the floor. Air intake is at
9 the bottom of the device below the sterile operating field.
10 There's been a ton of evidence in this case that 3M knew
11 their filtration system was inadequate. They led people to
12 believe that it was hepa filtered, and in fact it wasn't
13 until 2016 after this case was well along the way that they
14 informed the FDA that in fact they did have a hepa filter,
15 and it basically harbors bacteria and pathogens, and that is
16 absolutely undisputed by 3M.

17 Underneath this, you've got two mechanisms by
18 which Bair Hugger increases the risk. You've got on the
19 bottom microbial contamination of the surgical field, and
20 you heard Mr. Blackwell talking about, well, plaintiff
21 should have done their own testing. They should have done
22 agar plates and seen whether bacteria lands on an agar plate
23 in higher numbers when the Bair Hugger is on.

24 We didn't need to do that study because the
25 studies exist, and you can see them set forth in Jarvis's

1 report, as well as Samet's. You have the Tumia study, the
2 Moretti study, the Zink study. All of those show that when
3 the Bair Hugger is on, the agar plate near the surgical site
4 show an increase in bacteria.

5 The Oguz case, the one from 2017 that
6 Mr. Blackwell, put up, showed that with respect to plate 4,
7 there were six plates in that study. Plate 4 was the only
8 plate that was at the surgical site, the hypothetical
9 surgical site. That was the plate that showed a substantial
10 increase in the bacteria on that plate, and that's, the
11 other plates were at different locations in the OR. That
12 plate, plate 4, you can read the study, shows that there was
13 an increase there.

14 Dr. Jarvis also talked about the Bernard study.
15 That was a case in which there was an outbreak of
16 *Acinetobacter baumannii* in the hospital, and they traced the
17 infection back to both the Bair Hugger device. The dust in
18 the Bair Hugger device carried that exact pathogen, as well
19 as some dust in another piece of equipment in the OR.

20 The Wood study cites Moretti and says there is an
21 increase, a substantial increase in bacteria on the agar
22 plates when the Bair Hugger is in use.

23 MAGISTRATE JUDGE NOEL: Can you just direct me
24 where in the memos do you recite all of these studies
25 showing an increase in bacteria?

1 MS. CONLIN: I think, and I can pull it up. I'll
2 have Mr. Sacchet pull it up for me, but I think it starts on
3 page 41. It might be a few pages beyond that, but I will
4 pull it up and show you.

5 MAGISTRATE JUDGE NOEL: This is the memo in
6 opposition to their motion to exclude Samet's?

7 MS. CONLIN: It is, Your Honor. And then the
8 other place that you can look for it is, you can look at, as
9 an example, Dr. Jarvis's report where he talks about these
10 as well. You know, for example, the bottom of page 13 in
11 Dr. Jarvis's report says, The study did document an increase
12 in mean bacterial load values when the Bair Hugger forced
13 air warming was employed.

14 So I don't have a nice table for you, but it is
15 interspersed throughout briefings and our expert reports.

16 MAGISTRATE JUDGE NOEL: Okay. Thank you.

17 MS. CONLIN: Page 46. I was off by five pages,
18 Your Honor.

19 MAGISTRATE JUDGE NOEL: Thank you.

20 MS. CONLIN: Other independent studies have
21 further found that the Bair Hugger increases both particles
22 and bacteria at the surgical site, Moretti 2009, Samet
23 deposition citing Moretti, the Wood and Tumia. It goes on
24 from there, Your Honor.

25 MAGISTRATE JUDGE NOEL: Okay. Thank you.

1 MS. CONLIN: The top of the chain causation is
2 disturb uni directional flow, and again not simply relying
3 on McGovern for that proposition. You have McGovern, which
4 did do a bubble buoyancy test, but you also have Legg,
5 Dasari, Belani, all showed a substantial disturbance of the
6 uni directional know which is considered ideal for
7 orthopedic surgeries, and of course you have Dr. Elgabishi's
8 analysis, our expert who did his own CFD analysis. He ran
9 his CFD analysis on a computer of which there's only ten.
10 There is a handful in the country. He used two million
11 hours of CPU processing time to run his simulation.

12 I doubt any of that was in front of the FDA, and
13 I'm going to talk about that a little more. Then you go on
14 to the increased dose of infectious organisms, again not
15 simply relying on McGovern, but there are two studies that
16 have come out, Stocks and most recently the Darouiche study
17 from 2017, and I'm going to talk about that.

18 But basically what that study showed was, if you
19 take a cubic meter in an operating room, for every ten in a
20 cubic meter, CFUs, increase in CFUs, the colony forming
21 units, so ten particles in that cubic meter carrying
22 bacteria doubles the risk for infection, and we relied on
23 that study, which hasn't been talked about.

24 And then you get to increased risk, and that's
25 where McGovern comes in, and it does because what Samet,

1 Dr. Samet used and Dr. Jarvis used McGovern for was to
2 quantify the risk based on this mechanism of causation, and
3 it's not just our expert's word for it. Mr. Ciresi put this
4 up, but these are what the parties agreed to in this case
5 through depositions or through their experts.

6 You only need one, as high as ten, but one will do
7 it to cause an implant in a prosthetic joint. Airborne
8 contamination is how it gets there. Bair Hugger harbors
9 infectious pathogens. 3M's witnesses said absolutely we
10 know it does, and it increases the particles over the
11 sterile field. Their 30(b)(6) witness said absolutely it
12 does.

13 Increased particles cause increased bacteria,
14 their experts admitted to that, and increased bacteria
15 causes an increased risk, and at the bottom here is a cite
16 to the Darouiche 2017, and by the way, that was a randomized
17 clinical trial, the gold standard that 3M got up today and
18 talked about and said there isn't anything.

19 Darouiche is the gold standard under their
20 definition, and what it showed and what it said was that for
21 every ten more colony forming units per metered square
22 increases or approximately doubles the probability of an
23 implant infection, and it gets back to the point Mr. Ciresi
24 was making this morning which is, they've never done any
25 testing to ascertain whether the Bair Hugger is appropriate

1 for use in orthopedic surgeries.

2 They haven't done it. You know from the document
3 I just put up that in back in 2007 they knew that it might
4 be contra indicated for orthopedic surgeries, and they
5 haven't done any studies, no studies whatsoever. They have
6 Dr. Sessler, part of their medical advisory panel say,
7 please do a study. They refuse. Do you know why they
8 refused? Because Dr. Sessler thought the air coming out of
9 the Bair Hugger was sterile. He testified to me in his
10 deposition to that. He didn't realize that the air coming
11 out was dirty. He didn't realize that it caused this
12 basically turbulence and convective currents in the
13 operating room.

14 So Dr. Elghobashi's analysis, which confirmed some
15 of the smaller studies, but it used a high fidelity, large
16 ed simulation to study the interaction of the Bair Hugger
17 use in the OR and what it does with the air movement. When
18 the Bair Hugger was off, the operating room carried on as
19 intended and as designed. When the Bair Hugger was turned
20 on, it showed large levels of turbulence intensity which
21 matters because in orthopedic surgeries in particular,
22 everything below the operating table is considered
23 unsterile. In fact, you'll hear stories from physicians
24 that if one of the aids in the OR in an orthopedic surgery
25 drops their hands below the table, they're required to go

1 out and scrub in again.

2 So basically what Dr. Elghobashi did, and I'm just
3 going to show you one slide from his rather lengthy report,
4 but this is not heat, by the way. If you look at this top
5 graph, I'll just represent to the Court, that's actually
6 turbulence. So a zero is a non-turbulent environment, so 60
7 is highly turbulent, so don't think of it as heat, think of
8 it as turbulence.

9 You can see with the Bair Hugger off, which is the
10 top one, and he ran that I think for 80 seconds. The
11 operating room is potentially -- or is operating as
12 intended. You've got the air flow coming down, and you can
13 see that it's pretty much in the non-turbulent area. Turn
14 the Bair Hugger, on and this is for 37 seconds only, and you
15 can see that in 37 seconds, you already have that degree of
16 turbulence going on, so what it's doing is essentially
17 pulling up all of the unsterile air from underneath that
18 operating table and dumping it in the surgical site, and
19 that's what his study showed.

20 Now, let me talk a little bit about third-party
21 research, all right. This is just some of the third-party
22 research. And Your Honor, you asked if we have a table, we
23 really don't, but these are sort of some of the key ones
24 that we see. Does the Bair Hugger increase particles at the
25 surgical site? 3M's author says -- or 3M's 30(b) (6)

1 witness, Al Van Derg, testified, quote, Every single study
2 indicates that the Bair Hugger increases the particle count
3 over the sterile field. That's 3M.

4 Sesler, 2011, one of the 3M's paid consultants, 3M
5 funded the study that he did, they also edited, I may add,
6 before it went to publication, also found increased
7 particles over the sterile field. And, in fact, when I
8 deposed Dr. Sessler, he said that the order of magnitude of
9 increased particles based on what he observed was 10 to 12
10 fold. That's what Dr. Sessler said on 3M's medical
11 advisory.

12 Legg 2012 and '13, increased the particle
13 concentration a thousandfold over the surgical site on
14 particles -- moving from particles to bacteria. By the way,
15 on particles, I think Your Honor asked the question this
16 morning, can particles be a proxy for bacteria? The Stocks
17 and Darouiche studies say absolutely, both of those are
18 peer-reviewed studies, that they absolutely act as a proxy.
19 But Dr. Wenzel, 3M's infectious disease expert in this case,
20 testified under oath that he believed that bacteria is
21 carried on nearly 40 percent of particles. That's what 3M
22 says.

23 Does it increase bacteria? I talked about this
24 before, but Moretti shows mean bacterial loads were
25 significantly increased from Bair Hugger use. Wood cited

1 Moretti and said yep, it's an increased bacterial load.
2 Tumia in 2002, higher bacteria at the surgical site as a
3 result of the Bair Hugger. And I talked about Darouiche so
4 I'm not going to go back to that again, but that's basically
5 how the chain of evidence goes.

6 MAGISTRATE JUDGE NOEL: Let me just ask this
7 question because I'm somewhat confused.

8 MS. CONLIN: Sure.

9 MAGISTRATE JUDGE NOEL: So obviously the
10 defendants base their whole attack on McGovern on various
11 citations to the depositions of these three experts, Samet,
12 Jarvis and Stonnington.

13 MS. CONLIN: Stonnington, yes, Your Honor.

14 MAGISTRATE JUDGE NOEL: And they cite places where
15 each one says that their opinion does depend or does rely on
16 McGovern. If what you're saying about Darouiche and Moretti
17 and Tumia are true, why didn't they say no?

18 MS. CONLIN: Well, what they said, and if you look
19 at the testimony very carefully, and this is sort of the
20 slight of hand that has been going on in this briefing, what
21 they each said, and it's an absolutely truthful statement,
22 is that the odds risk ratio, the percentage or the
23 quantification of that amount of increased risk is based on
24 McGovern because it's an apples-to-apples comparison because
25 it's, you know, conductive warming to forced air warming.

1 They used it, and if you go back and look at their
2 depositions, they say I used that to calculate the odds risk
3 ratio to quantify the risk. But, yes, you could definitely
4 say that even if McGovern didn't exist, the Darouiche 2017
5 study would show that if you can prove that there's more
6 particles over the surgical site in use, for every ten it
7 doubles the risk, but our experts did rely on McGovern for
8 quantifying that odds risk ratio.

9 You know, we heard this -- we saw slides that had
10 causation X'd out and X'd. Epidemiological studies don't
11 show causation. They show association. This is from the
12 same reference manual that Mr. Blackwell cited to this
13 morning, an association is not equivalent to causation.
14 Causation is a judgment for epidemiologists to make based on
15 the totality of the scientific evidence. And that's why you
16 see in McGovern, they say we say there's an association
17 because they're looking at one group of patients and they're
18 saying we see an association. It's for the epidemiologist
19 to come in, look at all of the evidence, look at all of the
20 literature outside of that, and make a causal determination.
21 That's what was done here. And in fact, their experts
22 agree, deciding whether associations are causal typically is
23 not a matter of statistics alone but also rests in
24 scientific judgment. And the Hill criteria that our experts
25 relied upon is well-known, not novel, and is used in a

1 number of cases.

2 Now, they talked about the *Viagra* case, and they
3 said, well that's one of those cases where they came back in
4 and they realized that there were problems and they told the
5 litigants that they couldn't rely on it. Very different
6 situation with respect to the study underlying that. That
7 was a case in which there was an allegation that *Viagra*
8 causes NAION or vision loss and they had a study. What they
9 found out was that some of the participants had vision loss
10 before they ever took *Viagra*. That's not the issue here.
11 In fact, both 3M's experts, Dr. Borak and Mr. Holford, said
12 that temporality is met in this case.

13 And I mentioned this before, but the cases are
14 replete where opposing experts often interpret the same
15 different studies differently. That's why you have a trial.
16 That's why you have subject to cross-examination. The jury
17 is, at the end of the day, is to make those final
18 determinations.

19 The McGovern study. Most of the morning was spent
20 on the McGovern study. I'd like to spend a few minutes on
21 it. It was peer reviewed, showed a strong association
22 between Bair Hugger and DJI. This evidence from McGovern
23 shows that it basically increased the risk of an infection
24 if you use the Bair Hugger 3.8 times, tripling the risk.
25 And there was 1437 patients, a fairly robust study.

1 And what's curious about this before I go onto the
2 details of McGovern is that of all of the studies that 3M
3 put up this morning and said that we're presenting some sort
4 of theory that doesn't pass muster under their view of the
5 world, there isn't a single epidemiologic study that
6 contradicts or disproves the association between Bair Hugger
7 and deep joint infections. 3M doesn't have any evidence.
8 So McGovern alone dictates that this goes to the jury.
9 Talked about that a little bit.

10 I want to talk to you a little bit about the
11 McGovern authors. These are the people that 3M is accusing
12 of academic fraud. I think it was -- the word "fraudulent"
13 was used. The word, you know, "lying" was used. The
14 word --

15 THE COURT: Setting aside the words, the graphs
16 that were shown to us just before lunch, do you have any --
17 is there any evidence that those don't say what they were
18 shown to say?

19 MS. CONLIN: Yes.

20 THE COURT: And the Figure 7, the history of
21 Figure 7.

22 MS. CONLIN: Yes.

23 THE COURT: Can you tell us what, if anything, is
24 inaccurate in the defendants' presentation about the
25 previous iterations and the Figure 7?

1 MS. CONLIN: Yes, absolutely. Let me go to that
2 and then I'll back up.

3 One of their attacks is these tabulation error
4 that maybe there was one more in each thing or in each
5 period. Basically, if you look at Figure 7, because one of
6 them was, oh, they took --

7 THE COURT: They took the 15th, yeah.

8 MS. CONLIN: So if you look at, I'll tell you what
9 we think happened. We think that it was a miscoding of the
10 year because if you look at Figure 7 in the McGovern report
11 and you compare it to the draft that was put up, there's,
12 let me just show you, between those two, there's one more
13 dot over here which suggests that what it was the year was
14 miscoded which is why it ended up where it is, but that's
15 where the new dot came up in the final dataset.

16 THE COURT: That's not the Figure 7 from the final
17 report though.

18 MS. CONLIN: Yeah, this is Figure 7 from McGovern,
19 Your Honor. You may have been looking --

20 THE COURT: So you're pointing up to the dots up
21 above the --

22 MS. CONLIN: Yeah. So they made much ado about,
23 you know, this graph as if it was --

24 THE COURT: How can you tell that one of these
25 dots is associated with that?

1 MS. CONLIN: You have to look very carefully
2 between the dots on the draft McGovern manuscript that
3 Mr. Gordon put up and this one and that's where it appears.

4 THE COURT: Do you want to do a side by side? Do
5 you have those? That's what you need, you need to take the
6 previous one and then you can find up there, there's going
7 to be one more little dot there?

8 MS. CONLIN: Yeah. And in fact, Your Honor, this
9 is Mr. Sacchet is going to get into this in great deal in
10 connection with his motion on Doctors Borak and Mr. Holford,
11 but he's going to walk you through that.

12 Now, here's where it lands at the end of the day.
13 Dr. Samet said one more, one less in each group doesn't move
14 the needle in terms of the overall conclusions of McGovern,
15 the author said that, and in fact, 3M's experts said that as
16 well. Professor Holford said one more, one less, it doesn't
17 matter.

18 The other issue that they say is that they
19 fabricated the start date. Again, pretty serious
20 allegations to be --

21 THE COURT: No, they compared the differences in
22 the statistical outcomes with one start date versus another.

23 MS. CONLIN: Yeah, but they -- Mr. Gordon said
24 this morning it's fabricated.

25 THE COURT: Right, well, just compare the Figure 7

1 that has the infection data to the draft. Yeah, the draft
2 has the number with the peak in 2010 and then the final has
3 this flat line infection rate percentage.

4 MS. CONLIN: Well, it's basically just taking an
5 average, but if you look --

6 THE COURT: It doesn't say average. It says
7 infection rate percentage, and it purports to show it over
8 time, July '08, January '09, July '09, and it doesn't --

9 MS. CONLIN: It's in the box right above it, Your
10 Honor. It says "raw case data." That's where the dots come
11 from, so they're showing exactly when the infections
12 occurred along this timeline, and underneath it, it says
13 average infection rate during period percentage.

14 THE COURT: But the dots are above any -- you've
15 got no way to quantify those.

16 MS. CONLIN: Well, it's quantified as a matter of
17 statistics. What they did here --

18 THE COURT: It's not a matter of statistics. It's
19 an average. It just shows -- what the defendants are saying
20 is you get a different average if you take different
21 numbers. I mean, that's not -- nothing remarkable about
22 that. If you -- you're going to get a different average if
23 you start in July of '08 versus if you start in September of
24 '08.

25 MS. CONLIN: Yes. And what I'm saying is and

1 that's where I was going which is Dr. Reed testified under
2 oath in this case that the reason that they started the data
3 on July 1st of 2008 was that was the first time that they
4 had full-time surveillance for infections amongst these
5 three hospitals. In other words, before that time, there
6 was some ad hocness to it, some were reporting, some
7 weren't. And he testified, and it is unrebutted, that he
8 started -- they started that date because of the fact that
9 was the first time they had full-time surveillance available
10 for the ones at hospital. And, you know, Mr. Sacchet is
11 going to put up the testimony on it, but that's what they
12 said.

13
14 So, I mean, you look at these three authors,
15 you've got Dr. McGovern basically standing behind the study.
16 You have Dr. Reed standing behind the study. And Dr. Read,
17 in fact, did further investigation and published on his own
18 a couple of studies post-McGovern on the two confounders,
19 one on the prophylactic antibiotics as well as the
20 antithrombo regimen, and said I can conclusively rule out
21 those two as confounders in that study.

22 You have Dr. Belani who is here in Minnesota at
23 the University of Minnesota, you know, head of
24 anesthesiology, he says, I've looked at this, I stand behind
25 this work.

1 You have Dr. Nachtsheim at the Carlson School of
2 Management here in Minnesota, he's looked at all of the
3 data, I stand behind the conclusions in the McGovern paper.

4 And you have Mark Albrecht, we gave you a better
5 photo of him, who, by the way, we haven't had the chance and
6 haven't questioned in this case because he was subpoenaed by
7 3M. He spent seven hours under questioning by 3M and he got
8 up and left when the seven hours were up, and so he is
9 somebody that we anticipate subpoenaing for trial, but we
10 haven't had a chance. But one of the things that he says,
11 because they talked about this tabulation error look, and
12 they're like, look, there's a problem here. He said -- 3M
13 says I don't know if that's the final data or not, and he
14 says I don't either. I mean this is a guy who was working
15 his way through school. And by the way, that consulting
16 agreement they put up postdates McGovern so you can set that
17 aside. That consulting agreement that Mr. Blackwell waved
18 around with great fanfare was signed after the McGovern
19 study. But this is --

20 THE COURT: Well, the McGovern study is the one
21 that says that authors of this have a financial interest in
22 the outcome.

23 MS. CONLIN: Yeah, yeah, yeah. Well, and they
24 said that, judge, because Albrecht was working part-time at
25 Augustine when he was getting his MBA from Minnesota. He's

1 one of the students of Dr. Nachtsheim.

2 THE COURT: Is there anything in the record to
3 indicate that's the reason that that disclaimer was put on
4 there?

5 MS. CONLIN: That -- none of these other authors
6 have any connection to Augustine so, I mean --

7 THE COURT: The record contains the disclaimer.
8 Does the record contain an explanation of the disclaimer?

9 MS. CONLIN: No, not to my knowledge. And if I'm
10 wrong, I think Mr. Sacchet can correct it, but all the
11 authors were not paid by Augustine. Dr. McGovern testified
12 that in connection with running the study, he actually ended
13 up losing money on it. There isn't anybody who's ever
14 worked at Augustine or had any connection to him outside of
15 this litigation -- or out of this McGovern study.

16 So we talked a little bit about this, but the bulk
17 of statistical studies seen in court are observational.
18 That's straight out of the reference manual. And Mr. Ciresi
19 touched on this, this morning, but 3M's refused to do the
20 randomized controlled trial.

21 So tabulation error doesn't move the needle, and
22 I'm going let Mr. Sacchet delve into the details on that.

23 Hypothetical confounders, Dr. Read and others have
24 testified they weren't confounding. And, in fact, what's
25 interesting about this argument is 3M has no scientific

1 evidence to suggest that these are confounders. It is pure
2 speculation on their part, and the studies that do exist
3 suggest that none of the changes in the antibiotic regimen
4 or the antithrombo protocol map, and you have to have some
5 sort of meaningful relation before you can argue it's a
6 confounder and when the study authors are saying I've done
7 more work and in fact they're not confounders
8 post-publication, they don't have anything to go on. And in
9 fact, their experts admitted that in the depositions, and
10 you'll see some of those admissions when Mr. Sacchet gets
11 up. And at best, the challenges go to the weight of Dr.
12 Samet, I would say as well as Dr. Stonnington, Dr. Jarvis,
13 the weight of testimony on McGovern, not its admissibility.

14 Now, I want to, unless the Court has other
15 questions on McGovern, I want to end on a couple of points
16 since they came up in connection with some of the briefing.

17 THE COURT: Just before you leave McGovern, what
18 do the study authors say, if anything, with respect to the
19 statement, "Unfortunately, recordkeeping was incomplete for
20 the additional factors of blood transfusion, obesity,
21 incontinence, and fitness for surgery"?

22 MS. CONLIN: They said they don't think it moves
23 the needle, and that's what Dr. Samet said as well. And if
24 you look above it --

25 THE COURT: But did they say why they wouldn't

1 think that would move the needle?

2 MS. CONLIN: Well, because you've got 1437
3 patients so you've got a fairly high group. The surgeries
4 were, you know, conducted over relatively short timeframe,
5 and it says demographics revealed no significant difference
6 between the two types of warming for SSI risk factors of
7 age, type of surgery, diabetes, and the late pre-operative
8 state.

9 THE COURT: If it doesn't matter, why would they
10 go on to say unfortunately?

11 MS. CONLIN: Well, I think they were being
12 cautious like a good researcher does which is why they said
13 hey, we've also got these potential confounders and the
14 change in antibiotic regimen and the anti-thrombo regimen,
15 so they disclosed it all. They put it out there and said we
16 want everybody who's reading this to know about those
17 particular confounders. But in point in fact, whether
18 you're diabetic, whether you're obese, you don't just get an
19 infection because of that. You have to have bacteria
20 landing on the implant before you will ever have an
21 infection.

22 THE COURT: Well, can't you have bacteria in there
23 already? Didn't one of your experts say that at some point
24 from the CDC?

25 MS. CONLIN: No, you're putting an implant in so

1 no. I mean, the cause of PGI's are things being introduced
2 during the operation onto that implant. So finally --

3 MAGISTRATE JUDGE NOEL: One last question on that.

4 MS. CONLIN: Sure.

5 MAGISTRATE JUDGE NOEL: Because it's been bugging
6 me all morning, and maybe this isn't the right time or
7 you're not the right person, but is every plaintiff suffer
8 -- does every plaintiff in the MDL suffer from a deep joint
9 infection as opposed to some other surgical site infection?

10 MS. CONLIN: Yes, Your Honor.

11 MAGISTRATE JUDGE NOEL: Okay. Thank you.

12 MS. CONLIN: And so the reason why it's created
13 during surgery is because the wound is closed up. It's
14 stitched up. There isn't bacteria entering once that's
15 stitched up. Now, you might get an infection on the top
16 surface or whatever, but if you have a deep joint infection,
17 something landed on that implant during the surgery, and you
18 don't just have bacteria on an implant because you're obese
19 or diabetic; it has to land there. Now, it might increase
20 your risk of getting an infection, but without -- and
21 Dr. Jarvis is very clear about that, without bacteria being
22 introduced during surgery, you're not going to have an
23 infection.

24 THE COURT: Was Jarvis the one who was at the CDC?

25 MS. CONLIN: Yes.

1 THE COURT: So when he was at the CDC, though,
2 didn't he say that deep joint infections come from bacteria
3 that's already in the patient?

4 MS. CONLIN: No, he said surgical site infections
5 can come from. He wasn't talking about deep joint
6 infections. And that's been a -- again, a slight of hand
7 and a conflation on that. And if I'm wrong, I'm sure
8 Mr. Sacchet, but that's my recollection of it so --

9 JUDGE LEARY: Let me ask this, you know, one of
10 the overriding concerns I have has to do with obviously
11 Rule 702, Daubert, and Frye-Mack, and the issues we have to
12 consider as judges and I have to consider with regard to
13 Frye-Mack is basically whether or not there is scientific
14 reliability to the theories offered by the plaintiff and
15 whether or not they're generally accepted within the
16 relevant scientific community. And I think many of us are
17 familiar with the expression that a collection of facts does
18 not add up to science. And that's the thing that I struggle
19 with most in hearing any argument presented with regard to
20 what is the alleged science in this case. We do have the
21 FDA letter. We do have the ECRI Institute. We've got the
22 consensus, the strong consensus of that international body,
23 and I haven't heard anything from the plaintiffs' side that
24 serves to undercut the conclusions that they have come
25 apparently looking at the same evidence. I'm not hearing

1 anything -- I'm not hearing the plaintiffs suggest that
2 those organizations have any less access to the same
3 information that the plaintiffs' experts are looking at.

4 MS. CONLIN: We don't know what the FDA reviewed,
5 and 3M has refused to tell us know what the FDA reviewed,
6 but let me address --

7 JUDGE LEARY: Let's talk about the ECRI.

8 MS. CONLIN: Yeah, ECRI --

9 THE COURT: And the international group, they went
10 through and explained a lot of what they looked at.

11 MS. CONLIN: And Michelle Hulse Stevens came back
12 to 3M and said this is an issue, we've got --

13 THE COURT: That's one person's statement about
14 what they heard as opposed to an actual report. There's a
15 difference in terms of the hearsay admissibility.

16 MS. CONLIN: Well, she's head, but let me address
17 the ECRI first. And we set this out in our reply brief.
18 The ECRI Institute wanted to do their own study, and the
19 documents, you can see in our reply brief, 3M shut them
20 down. They said the last thing we want is ECRI doing it.
21 They sent them stuff which they hold in their documents one
22 sided yet competitive, and then they were allowed to edit
23 the ECRI document before it was published. So --

24 JUDGE LEARY: Well, here's -- when you -- and with
25 all due respect, when you make comments like that, that

1 really strikes me as lawyer argument, the very thing that
2 *Glastetter* warns against, and it does not in any way
3 undercut what ECRI chose to do. There's no one in this room
4 that disputes the attempt at objectivity of the ECRI
5 Institute regardless of. Whether or not the information
6 you're suggesting is accurate, there's no reason to suggest
7 that it in any way altered the recommendation of the ECRI
8 Institute.

9 MS. CONLIN: Well, ECRI this year did an ECRI
10 update, you're getting warm, uncovering forced-air warming
11 units, same organization. They said a warming unit should
12 have a HEPA grade or better filters to reduce the risk that
13 airborne dust, bacteria, and mold will be blowing onto the
14 patient or into wounds. That's --

15 THE COURT: What exhibit is that?

16 MS. CONLIN: I'll pull it out, Your Honor. I'm
17 going to have somebody pull it out.

18 THE COURT: Okay. But doesn't it say on the top
19 what ECF document it is?

20 MS. CONLIN: I don't have it here. If I might
21 approach, I can hand it up.

22 THE COURT: Well, I can pull it up myself if you
23 tell me what the docket number is.

24 MR. BLACKWELL: May we see that, Your Honor? We
25 don't think that's in the record.

1 MS. CONLIN: It's Plaintiff's Exhibit 64.

2 THE COURT: To what?

3 MR. BLACKWELL: To what?

4 MS. CONLIN: To our opposition to the motion to
5 exclude --

6 THE COURT: Which is docket number what?

7 MS. CONLIN: It's a motion to exclude Samet,
8 Borak, and Stonnington.

9 THE COURT: I'm looking at the numbers. I need a
10 number, docket number.

11 MS. CONLIN: I'll pull it up, Your Honor. While
12 they're pulling that up, I'll address Your Honor's direct
13 question. It's not just -- the studies are consistent.
14 This isn't a novel theory. The studies are consistent. You
15 use the Bair Hugger, you're going to have more particles and
16 bacteria over the surgical site. The McGovern --

17 JUDGE LEARY: When you say that, you seem to be
18 neglecting a number of studies from reputable organizations,
19 including the FDA and the ECRI Institute.

20 MS. CONLIN: Well, they haven't -- with all due
21 respect, I don't know what the FDA looked at. I mean, I
22 don't, and I think that would be fair game, but the ECRI
23 Institute doesn't have the admissions of 3M that, yes, their
24 studies and every single study they've seen shows an
25 increase in particles when the Bair Hugger is in use.

1 That's not an uncontested fact.

2 JUDGE LEARY: So, you know, I'm just trying to
3 make a point from -- a point of view of a judge deciding
4 whether or not the information being presented is
5 scientifically reliable and whether or not it's generally
6 accepted. We have to take a look at what is out there, and
7 as *Glastetter* says, there may be a forcible argument that
8 can be made that somewhere down the road general causation
9 can be established, but we're not here today, and that's
10 what is of concern to me. I don't ultimately care who's
11 right or wrong in terms of who wins or loses on this issues.
12 I'm just concerned about our obligation to accurately
13 understand the reliable science as opposed to lawyer
14 argument. And when you look at the science, I see a lot of
15 argument, but I don't see anything that undercuts FDA, ECRI,
16 or the opinions of the international conference.

17 MS. CONLIN: Well, I mean, McGovern does give you
18 the odds risk ratio, but you do have Darouiche and Stocks
19 and all the other studies that we showed and that's how
20 epidemiology works which is you take, in our case --

21 JUDGE LEARY: But doesn't the FDA understand that?

22 MS. CONLIN: No, they --

23 JUDGE LEARY: Doesn't the ECRI substitute
24 understand that? Don't all of the attendees and voters at
25 the international conference, don't they understand that?

1 MS. CONLIN: Well, you know, on ECRI, you know --
2 and by the way, Your Honor, the docket number is 910-53,
3 Exhibit 64. ECRI says you should have a HEPA filter which
4 we know 3M does.

5 THE COURT: The docket number is 879 actually.

6 MAGISTRATE JUDGE NOEL: No, no, no, she's -- PX-64
7 refers to an exhibit of a declaration or --

8 MS. CONLIN: Yes, it's an exhibit to a
9 declaration.

10 MAGISTRATE JUDGE NOEL: And the docket number you
11 gave was?

12 MS. CONLIN: 910-53. And, Your Honor, it's on the
13 last page of that document, the last paragraph.

14 THE COURT: All right. Thank you.

15 MS. CONLIN: The last sentence.

16 While the Court is pulling that up, the FDA only
17 has available to it what manufacturers give it. It doesn't
18 have, like the CDC or some organizations, an ability to go
19 out and conduct their own research. They rely on what is
20 given them, which is why the Bair Hugger was first approved
21 based on a 1937 cast dryer because they have to rely on what
22 the manufacturers are saying to them which is why the FDA
23 going one way or another, the courts have been very
24 consistent on that, doesn't impact whether a matter is ripe
25 for the jury or not.

1 MAGISTRATE JUDGE NOEL: I'm sorry, Ms. Conlin, was
2 it 910-53, Exhibit 64?

3 MS. CONLIN: And while they're pulling that up,
4 Judge Leary, there is a difference between methodology and
5 conclusion. The methodology that our experts employ in this
6 case is not novel, is well grounded in science. What the
7 issue is the conclusions. And the conclusions, as long as
8 the methodology is sound and reliable, the conclusions that
9 you draw from that are for the jury, and I think the cases
10 both under Frye-Mack as well as the Daubert standard support
11 that.

12 Do you have it, Your Honor? Okay. It was cited
13 in our papers.

14 Lastly, I just want to conclude with a couple of
15 the sort of slight of hand issues that I just want to point
16 out for the Court. The top of this is on the tabulation
17 error, and 3M writes SJS do not dispute that when the
18 tabulations errors are corrected, the association between
19 the Bair Hugger system and infections disappears. That's
20 not true. In fact, Professor Holford testified that if you
21 correct the tabulations errors, your still over 2.0, and
22 that, in fact, is borne out in the testimony that we have
23 cited this.

24 MAGISTRATE JUDGE NOEL: That was the question I
25 had this morning for Mr. Blackwell and he gave me a

1 different answer. So explain to me again the difference
2 between -- he thought that the 2.76 number was simply
3 accounting for, even assuming the correctness of the
4 McGovern data, and you're telling us -- and then he said
5 then that all of your witnesses agreed that if you accept
6 their corrections to the McGovern data, that it does go to
7 zero.

8 MS. CONLIN: No, we don't agree with that.

9 MAGISTRATE JUDGE NOEL: Work those numbers through
10 for me. Who says what?

11 MS. CONLIN: Sure. Okay. So this is, at the
12 bottom of this page is a footnote out of Professor Holford's
13 report, and this addresses -- well, is there one more --
14 it's at the very bottom it's small because it's a footnote
15 from Professor Holford's report from 3M, and basically he
16 said, well, if there's one more infection in each group I'm
17 going to calculate that out, and he still has a odds risk
18 ratio of 2.86.

19 Professor Holford also testified that even if you
20 accept the confounding evidence, it's still got more than a
21 doubling of the risk on that, and Mr. Sacchet is going to
22 get into that in great detail in connection with the next
23 presentation.

24 MAGISTRATE JUDGE NOEL: Okay.

25 MS. CONLIN: The other thing, just to point out,

1 they say that we dismiss *Glastetter* as unsigned per curiam
2 opinion with no legal effect. With all due respect, we
3 didn't say that. If you look at what we actually wrote in
4 our brief which is at the bottom of the slide, we said,
5 Citing only *Glastetter* and science per curiam opinion,
6 defendants insist that, blah, blah, blah. And we said, The
7 defendants not only misstate the legal standard for medical
8 testimony or Daubert, they misread *Glastetter*. We never
9 said it had no legal effect. In fact, we spent the next
10 two pages in our brief explaining *Glastetter* and what we
11 think. We said that 3M misread it. We didn't say it had no
12 effect under the law.

13 They also go in their brief, and this is in their
14 reply brief, they say, We also argue there's a land slide of
15 cases contrary to *Glastetter*. Well, if you look at your
16 actual brief, and these are two chunks from page 13 and 14,
17 we're talking about McLean's conclusive study. And they do
18 that throughout there where we are accused of things we
19 never said or there's a statement that says we admit it and
20 there's no citation to anything.

21 And, finally, in their reply brief, they go
22 through and say over and over again, and this one
23 particularly sat in my coffer, reasons that are -- should be
24 obvious to this Court, but they keep saying that the
25 analysis of Professor Holford and Dr. Borak were unrebutted.

1 Well, we contest those opinions, and you're going to hear
2 from it in connection with Mr. Sacchet's presentation.

3 The reason why we don't have rebuttal reports is
4 because the Court told us we couldn't file them, and so I do
5 think it's a bit disingenuous to come and say that their
6 expert opinions are unrebutted because we didn't as a
7 procedural vehicle have an opportunity to file a rebuttal,
8 but we do dispute what Dr. Borak and Professor Holford
9 concluded.

10 And when you see the admissions that they made in
11 their depositions about the variation that Mr. Gordon
12 raised, there will be no doubt in your mind that this attack
13 on McGovern is not based in fact and it's not based in
14 science and every single one of those authors who are
15 esteemed in their field.

16 I mean it's interesting because I was at
17 Dr. Belani's deposition and I actually had documents where
18 3M was so mad when that came up that they thought they were
19 going to go and attack Mr. Belani, and I showed him those in
20 the deposition and he was absolutely mortified. He didn't
21 know that there was an internal plan to try to discredit him
22 or his work and he was highly offended by it. But this has
23 been an unbelievable and unfair, because it's not borne out,
24 attack on the McGovern's authors. It is peer reviewed,
25 published in a key journal, a journal which Mr. Blackwell

1 cited peer-reviewed study after peer-reviewed study, none on
2 point, by the way, they weren't looking at prosthetic joint
3 infections or the Bair Hugger, but saying that's the gold
4 standard, said that randomized clinical trials are the gold
5 standard. Well, Darouiche shows that if you increase the
6 particles over the surgical site, if you get 10 CFUs, you're
7 going to double a patient's risk of infection, and 3M has
8 known that, 3M has refused to do the studies, and 3M has
9 continuously said Bair Hugger for everybody, use it in every
10 surgery when back in 2007 they already knew it was
11 contraindicated in orthopedic surgeries because of the very
12 small number of bugs it needs to cause a devastating
13 infection in the patients.

14 And I'm done unless Your Honors have other
15 questions.

16 THE COURT: Thank you.

17 MR. BLACKWELL: Your Honors, may I respond?

18 I particularly want to pick up where counsel left
19 off about things been stuck in her craw. I've got a craw
20 too, Your Honor, and there's some things sticking in it that
21 I'd like to get clarified right upfront. First of all, you
22 heard us spend a great deal of time putting up here study
23 after study on biological plausibility, number 17 that Your
24 Honors saw. Oh, I got to fix this. Study after study, and
25 it was clear that to the extent they are biological

1 plausibility studies, they don't support plaintiffs' theory.
2 And counsel just stood here and cited Moretti, cited Wood,
3 Tumia, Darouiche for the proposition that when the Bair
4 Hugger is turned on that bacteria is increasing. And these
5 studies do not say that. And in fact, the Darouiche study
6 isn't even a study of the Bair Hugger, to be clear about it.
7 And so that's the first thing sticking in the craw.

8 If Your Honors look at the language, and I would
9 suggest that the Court look very carefully at the language,
10 because in a hearing that's supposed to be about the
11 accuracy and reliability of facts and the data are not being
12 confounded by lawyer argument that complicates the thing.

13 And if you look at the actual language, if you
14 took one of these for example, the Zink study, and what the
15 authors actually found, and I quote, in Zink, in conclusion,
16 conclusion, the warming therapy, when properly applied, to
17 direct the flow of air away from the surgical site does not
18 increase the risk of wound contamination in the operating
19 room. That's what Zink says. If I look at what --

20 MAGISTRATE JUDGE NOEL: What's Moretti say?

21 MR. BLACKWELL: Moretti says, the Bair Hugger does
22 not seem to pose increased risk of nosocomial infections,
23 while it does offer the advantage of the potentially grave
24 consequence produce by hypothermia during major orthopedic
25 surgical procedures. The increased bacterial load found

1 after application of the body warming system appears to be
2 comparable to or lower than the load present at the time of
3 placement of the patient on the operating table.

4 So using the Bair Hugger, turning it on, either
5 leaves a bacteria load exactly where it was or lower.
6 That's what the study in fact says.

7 And I can't even stop there because this whole
8 ECRI study was brought up which is simply astounding. First
9 of all, to spend all their time talking about a filter.
10 They don't have a filter expert, so this is nothing but
11 purely lawyer argument. But if Your Honors in fact looked
12 at the language, that you couldn't have missed it because
13 it's right above the language they're referring to, where it
14 says, and I quote, they -- I'm quoting the wrong thing, Your
15 Honor. Let me back up.

16 THE COURT: But you feel really strongly about it,
17 whatever it is.

18 MR. BLACKWELL: It says, "There is an increasing
19 scrutiny of forced-air warming units and a possible link to
20 infection as a result of airborne contamination. While
21 studies have shown no proof of this, there is still a
22 concern that the blanket can increase a bacterial
23 contamination to the surgical site, but studies have shown
24 no proof of this. Why in the world do you bring up an ECRI
25 study for the proposition that somehow some proof when it

1 expressly studies have shown no proof? ECRI simply iterated
2 what it had said before. And to bring this up in the
3 context was not being candid with the Court, with all due
4 respect.

5 MAGISTRATE JUDGE NOEL: What about the 2007 3M
6 chart they showed of when Bair Hugger versus Bair Paws and
7 the benefits of the Bair Paw is that it's not going to cause
8 an infection?

9 MR. BLACKWELL: The Bair Paws is not the Bair
10 Hugger.

11 MAGISTRATE JUDGE NOEL: I understand that.

12 MR. BLACKWELL: It's a separate and completely
13 different product, and --

14 MAGISTRATE JUDGE NOEL: The point is that what
15 they were showing us in the exhibit, as I understand it, is
16 in attempting to sell the Bair Paws, one of the benefits was
17 that, unlike the Bair Hugger, it's not going to get
18 contamination into the site of an orthopedic surgery or
19 cardiac because it's just being used pre surgery and that's
20 one the reasons you should by a Bair Paw is --

21 MR. BLACKWELL: I can't speak to the Bair Paws
22 document expressly. I can't. One of my colleagues will.
23 First of all, the mere fact that a scientist says something
24 doesn't even make it scientific. The fact that a fact
25 witness or marketing person says it doesn't make it

1 scientific. It's not a proxy for science and studies. And
2 so if you look at the science, there simply is no there
3 there. It is literally Potemkin science. And the only way
4 they get at this idea and get anybody behind it is because
5 their lawyers and experts were paid, propping up the
6 village.

7 And if Your Honors were to drill down on what we
8 have here at bottom, the only way that the plaintiffs can
9 take the science that exists and have it support their
10 theory is to recast the science by lawyer argument or using
11 blue pencils. Confounders aren't really confounders in the
12 studies. A study that says that there is no causal basis
13 for positive association suddenly becomes a study that says
14 that the Bair Hugger is a causal basis for the association.
15 And then they cite studies like Darouiche that aren't even
16 studies of the Bair Hugger. That alone should cast a great
17 deal of skepticism on the plaintiffs' science --

18 MAGISTRATE JUDGE NOEL: They're not offering it
19 for that. As I understand Darouiche, the point they make is
20 that Darouiche stands for the proposition that if you
21 increase particle over a surgical site, you're going to
22 double the risk that bacteria is going to fall into and
23 cause a surgical infection, whether it's Bair Hugger or
24 anywhere else. What they're citing it for is the
25 proposition that particles are a proxy for bacteria because

1 if you increase the particles, you're going to increase the
2 risk of bacteria, isn't that what they're telling me?

3 MR. BLACKWELL: Well, Your Honor, what -- I want
4 to be clear what they're not telling Your Honors s if Your
5 Honors look at the nine studies that span a 25-year period
6 on the screen right now that are looking here at particles
7 emitted from the Bair Hugger, not some abstract, generic
8 sort of thing unrelated in any respect whatsoever to what we
9 specifically know about particles emitted from the Bair
10 Hugger, which is if all particles, no matter what degree,
11 carry bacteria, then why in the world can't they show Your
12 Honors one study involving the Bair Hugger where that's
13 true? There's only ipse dixit and generalities that have
14 nothing to do with defacing the body of science that are
15 specific to this product and this company and this case
16 which is what this really is about.

17 And so these generic kind of claims, epi studies,
18 and as we know, they don't conclude causation, there's the
19 confounders, in McGovern, it says so, so we believe it.
20 Particles carry bacteria. It's as if we don't know. Study
21 after study study the particles from the Bair Hugger and not
22 a single one of them has ever found bacteria. So before
23 they can meet their burden and get across you talk about
24 issues with the methodology, I guarantee you not a single
25 expert that the plaintiff has uses Bradford Hill for the

1 purpose of determining whether there is causation out in the
2 real world, and I guarantee they certainly don't use it for
3 purpose of deciding whether there is a positive association
4 even in the first place, and the law says they can't do it
5 here either.

6 MAGISTRATE JUDGE NOEL: So let me go back to the
7 question I asked you this morning and I got a different
8 question from Ms. Conlin which is explain to me this
9 confounder thing. I understand your answer was their
10 experts agree that if you account for the confounders that
11 you identify or that they identify in McGovern, the
12 association disappears, goes to zero. And Ms. Conlin says,
13 no, her witnesses don't say that, they say it goes to two
14 times instead of almost four times.

15 MR. BLACKWELL: Well, what can't really be argued
16 with, Your Honor, and you'll see this with Dr. Holford, is
17 that when you look at the period of time when the HotDog and
18 the Bair Hugger are being subjected to absolutely the same
19 residents, you'll see there is no difference in the surgical
20 site infection rate. And so that's not expert argument.
21 That's simply what the data shows and they are being both
22 subjected to the same anticlotting regimen and the same
23 antibiotic and regimen which they can't be argued with.

24 But irrespective of it, obviously even though I
25 say this doesn't come down to McGovern, it comes to

1 McGovern, given how much time we've spent talking about
2 McGovern, rightly so. Apart from this issue, and I don't
3 need to be completely parted from Your Honor's question,
4 it's fraught with many other problems and issues and the
5 comorbidities, the obesity, the fitness for surgery, those
6 areas were not addressed at all by their experts in any way,
7 shape, or form.

8 MAGISTRATE JUDGE NOEL: Right. Well, except as I
9 understand what Ms. Conlin tells me is that their experts do
10 address them by saying that those factors might increase the
11 observational risk of a surgical site infection or a deep
12 joint infection but without bacteria getting into the site,
13 those things do not cause a surgical site or deep joint
14 infection.

15 MR. BLACKWELL: With all due respect to the
16 argument counsel made, the fact is that the study authors
17 found that those items have quite an impact on the potential
18 development of infections that they weren't controlled for.
19 It wasn't a randomized study. The peer review was
20 considered that.

21 And if I may, Your Honor, we most certainly highly
22 contest an ocean that somehow the body is sterile but for
23 the implant that goes into it which introduces a bacteria.
24 We're going to show and the science is going to show, does
25 show, that the most common source of surgical site

1 infections, prosthetic joint infections, is their own
2 bodies, the sweat glands, the oil ducts. When you cut into
3 it, it's necessarily contaminated. When it becomes an
4 infection depends on the body immune systems, and that's
5 where all of these other factors come in, diabetes, this or
6 that, making one person more subject to developing a
7 full-blown infection than another, so we don't accept that.

8 MAGISTRATE JUDGE NOEL: Okay.

9 MR. BLACKWELL: And we certainly don't agree with
10 any of the statements they made that all the parties agree
11 that fill-in-the-blank, and so I won't go to rebut them all,
12 but we certainly don't agree.

13 MAGISTRATE JUDGE NOEL: But apparently they don't
14 agree with you every time you say all the parties agree
15 either.

16 MR. BLACKWELL: Except that I'm right, Your Honor.
17 And so I'll say, Your Honor, certain things are not
18 contested is what I will say, so when I say, for example --

19 MAGISTRATE JUDGE NOEL: What I'm trying to figure
20 out is what is not contested, and I have a hard time,
21 because you say some things are not contested that they
22 contest. They say some things are not contested that you
23 contest.

24 MR. BLACKWELL: You see -- in terms of what
25 matters on the screen right now, nine published studies that

1 address the issue of biological plausibility. If they can
2 get up and read to Your Honors even one of them involving
3 the Bair Hugger where they culture bacteria, then there's
4 else to really nothing to argue about. Either they have it
5 or they do not. So when I say that this study supports, I
6 invite them to get up and show Your Honors a story. I don't
7 mean lawyer argument or interpreting documents.

8 They had corporate documents in the *Glastetter*
9 case too, and the Court found that that was not sufficient
10 because you pick up a document, pair of scissors or paste
11 pot, cut out the things that you want to refer to and even
12 if it's in the context, it's simply one person expressing an
13 opinion and who knows what the foundation was, who knows how
14 credible it was, it's not science or correct. If a
15 scientist a said it. It doesn't make it science because a
16 another scientist says it. This issue --

17 THE COURT: What's the study that Ms. Conlin was
18 talking about where she said that with the Bair Hugger
19 turned on twice as many or -- either twice or ten times as
20 many bacteria landed in the petri dish?

21 MR. BLACKWELL: I think what was referred, was
22 that Moretti she was referring to? Or Darouiche? Or Oguz?
23 If it is Oguz, Oguz is the one I showed Your Honor that
24 concluded that there was no increase whatsoever in particles
25 whether or -- bacteria whether the Bair Hugger was turned on

1 or not.

2 THE COURT: I just don't understand how there
3 could be such different readings of the Oguz. We've got
4 Oguz somewhere in this material, right?

5 MR. BLACKWELL: By reading the language, Your
6 Honor, and I quoted the language when I put the Oguz study
7 here for Your Honors to say at slide No. 16 for Your Honors
8 to see exactly what Oguz says. And so this was the study
9 between, again, the Bair Hugger and the HotDog.

10 THE COURT: Yeah.

11 MR. BLACKWELL: You can fast-forward a bit now,
12 Brad, I'm sorry.

13 An important finding of our study was that the
14 type of patient warming did not influence the amount of
15 bacterial sedimentation on either plate keep. So going,
16 please. Okay.

17 THE COURT: Either of you implies that there's
18 two. I thought she was talking about four different plate
19 positions. How do we know that --

20 MR. BLACKWELL: Well, this was the punch line for
21 the Oguz study is here that the ultimate finding of the Oguz
22 study was that -- because I got there quicker, that's the
23 problem. A dastardly trick, Your Honor. So Oguz, which was
24 here, they explained what they did, recent peer-reviewed
25 published research in Oguz shows no association between Bair

1 Hugger use and increase in airborne bacteria. Not possible
2 to detect any higher bacterial counts on any plate, not one,
3 two, three, four, however many, no increased or higher
4 bacterial counts on any plate in the forced air warming Bair
5 Hugger group versus the resistive warming HotDog group.

6 And then Oguz has references. And Your Honors can
7 see that I would certainly invite Your Honors to study it
8 because this type of hearing given the issues of reliability
9 underlying expert opinion, I do not turn on lawyer
10 characterizations or slants on what the studies actually
11 say. And so here we're quoting Oguz, and if we have somehow
12 misquoted any part of it, please hold us in account for what
13 this study says. And so we carefully looked at all of these
14 before we made the statement that there isn't a biological
15 plausibility study that favors or supports the plaintiffs'
16 theory, and if there were, we would have been the only one
17 to have seen or found it, ECRI would have seen or found it,
18 as would have the FDA.

19 If I could briefly look at number 24 because there
20 keeps being a lot of statements made about we don't know
21 what the FDA looked at. We don't know everything that the
22 FDA looked at, but it's pretty clear, they say that what
23 they did in the second box, they collected and analyzed data
24 available to date from several sources, including medical
25 device reports received by the agency; information from

1 manufacturers and hospitals; publicly available medical
2 literature, which most certainly includes the ones we've
3 been discussing, given that the government was discussed all
4 over the place, the international consensus group to ECRI,
5 etc., addressed McGovern; separating and ventilation
6 requirements. So it doesn't tell you what specifically
7 everything that the FDA discussed, but it does say that the
8 FDA did look at the available medical literature, so we know
9 that much.

10 So, Your Honor, unless there are other questions I
11 will stop and sit down.

12 JUDGE LEARY: I do have a question that over time
13 I've been thing of repeatedly but it seems so simplistic
14 that I keep on thinking I shouldn't be reminded of it, but
15 let me ask you this question. It seems undisputed that all
16 -- both parties agree that maintaining normothermia during
17 prosthetic joint surgeries is a good thing and the science
18 behind it is reliable. Would you agree with that?

19 MR. BLACKWELL: I would agree with that, Your
20 Honor.

21 JUDGE LEARY: And that one of the benefits of
22 maintaining normothermia is it reduces the risk of infection
23 at the surgical site, correct?

24 MR. BLACKWELL: That's correct. And the FDA said
25 so in its letter.

1 JUDGE LEARY: So if the argument is that the Bair
2 Hugger is a defective device, if you will, is it the
3 argument that a Bair Hugger should not be used at all to
4 maintain normothermia?

5 MR. BLACKWELL: That would be in fact the
6 plaintiffs' argument and that some other warming therapy
7 should be used, not the Bair Hugger.

8 JUDGE LEARY: What I've heard so far today or what
9 I've read, there's no reason to suggest that the results
10 vis-à-vis infection are any better or any more improved than
11 the HotDog or any other device, nobody's really looked at,
12 other than in the context of the HotDog device. Is that
13 fair?

14 MR. BLACKWELL: I would say other than the Oguz of
15 course looks at both types of warming therapies, conductive
16 and convective, and comes to the conclusion that there was
17 difference in bacterial sedimentation.

18 And the FDA language which I just put up here at
19 the bottom with FDA continues to recommend using thermal
20 regulating devices which then it distinguished. It says
21 including forced-air warming device because it doesn't
22 distinguish.

23 JUDGE LEARY: And the last question or two I have
24 related to that is that if it's true that maintaining
25 normothermia reduces the risk of infection in surgical

1 sites, isn't the risk of infection using a device such as
2 the Bair Hugger, doesn't that reduce the risk more greatly
3 than not use to at all? In other words, even if you can
4 make an argument that the infection rate goes up if you pass
5 particles or air over the wound site, it still is an
6 improvement over not maintaining normothermia?

7 MR. BLACKWELL: It is, absolutely an undisputed
8 improvement over not maintaining normothermia and not just
9 SSIs but for all of the benefits too.

10 MAGISTRATE JUDGE NOEL: They're shaking their
11 heads.

12 THE COURT: And they say -- and I might be
13 misremembering their brief, but I think they said it was --
14 that that's only shown with respect to some kind of
15 colorectal surgery, if I'm -- and I'm sorry, I have read so
16 much, if I'm misremembering your brief, I apologize, but I
17 thought they said we don't buy that except -- we don't agree
18 that it's established that keeping an orthopedic patient
19 warm actually reduces, that everybody is just relying on
20 some old colorectal, which, you know, that seemed like there
21 would be a lot of infection in a colorectal.

22 MR. BLACKWELL: Your Honor, here's what's not
23 being debated about maintaining normal body temperature,
24 fatal heart attacks are reduced, blood transfusions are
25 reduced, length of hospital stay, post-operative shivering,

1 and surgical site infections, all reduced. And again, if
2 there is a valid science ultimately supporting the
3 proposition that this is not generally accepted in the
4 community, not just lawyer's arguing things for obvious
5 reasons, let them come forward with it.

6 And this is -- and it's so well established that
7 you'd be hard pressed, and they would too, to find a single
8 orthopedic surgery where the treating attending
9 anesthesiologist or treater is not going to be warming the
10 patient intraoperatively because it is so much now the
11 standard of care outside of this courtroom. It's not even
12 debate. This is a just simple lawyer's argument because
13 they don't like it.

14 MAGISTRATE JUDGE NOEL: Thank you.

15 MR. BLACKWELL: Thank you, Your Honor.

16 MS. CONLIN: Mr. Blackwell challenged me to come
17 up with the article, so I'd like to take the challenge. If
18 you look at the Moretti article, I'm quoting from page 4
19 that, In the clinic procedures in which the Bair Hugger was
20 used, the mean bacterial load values were significantly
21 increased.

22 THE COURT: Oh, so it wasn't Oguz.

23 MS. CONLIN: Well, I'm going to talk about Oguz in
24 a second.

25 THE COURT: All your friends told you it was Oguz.

1 MS. CONLIN: Yeah, well --

2 THE COURT: You need better friends.

3 MR. ASSAAD: It's both, Your Honor.

4 MS. CONLIN: Yeah, it's both, Your Honor. I mean,
5 this was only 20 patients, so they concluded that there
6 weren't more infections but it was such a small study that
7 you wouldn't expect to see one anyway. But they found that
8 with the Bair Hugger on, the main bacterial load values were
9 significantly increased on Oguz. They expressly said this
10 is not a statement of safety on the Bair Hugger, and it was
11 minor orthopedic surgeries less than an hour.

12 And I would urge the Court to look to the Table 2,
13 plate 4, which is the plate that's over the surgical site.
14 They did find a significant increase. What they found was
15 if you add all of the plates together, it was just barely
16 below statistical significance, but they did find at the
17 plate in a minor orthopedic surgery lasting less than one
18 hour an increased risk. The other thing I want to address
19 is --

20 JUDGE LEARY: Can you specifically report -- or
21 point to the language in that study that you characterized?

22 MS. CONLIN: Sure. It's Table 2, plate 4 in that
23 table, Your Honor. Oh the safety statement?

24 JUDGE LEARY: Just the words from the article.

25 MS. CONLIN: The study may obviously not be

1 generalized for an overall safety statement on forced-air
2 warming and it's primarily applicable in this particular
3 surgical setup.

4 THE COURT: It starts right off with a disclaimer,
5 it's not used the way we're being asked to use it, right?

6 MS. CONLIN: Correct. Now Judge Leary raised the
7 question of surgical site infections, and throughout this
8 case there has only been one study ever conducted that has
9 shown a lowering of a risk of surgical site infection due to
10 warming, forced-air warming in a hospital. That's the Kurz
11 study from 1996. We deposed Dr. Kurz and her co-author
12 Dr. Sessler. Both of them testified under oath that they
13 have absolutely -- they would not publish the study today
14 and they have absolutely no reason today to believe that
15 warming a patient during surgery reduces surgical site
16 infections.

17 And it goes to the point you made about the FDA
18 because the FDA says you should warm intraoperatively
19 because it reduces surgical site infections? Well, I don't
20 think the FDA knows that the authors of that study under
21 oath and cited in our brief disclaimed that study and said
22 we wouldn't publish it today and we know of no evidence that
23 suggests that warming during surgery lowers surgical site
24 infections, and that testimony is in our brief. And so it's
25 not central to the case because there's other ways of

1 warming a patient during surgery if you choose to or as the
2 FDA says, if you think it's warranted.

3 And the exact quote out of Dr. Kurz's deposition
4 is at page 179, line 16, it's Exhibit 59 to our brief. In
5 today's -- question, In today's scientific standard, there
6 is no reliable evidence that supports that maintaining
7 normothermia reduces the incidence of infection? Answer,
8 That is correct.

9 The FDA didn't know that. The FDA writes a letter
10 and says if you warm, it's going to reduce the surgical
11 site. And that's back to my point which is the FDA only
12 knows what only knows what is put in front of them and
13 absolutely they didn't have that evidence.

14 JUDGE LEARY: Well, let me ask you this. Would
15 you say that it's generally accepted within the orthopedic
16 community that maintaining normothermia is beneficial to a
17 patient's outcome?

18 MS. CONLIN: Yes, I would agree that that's the
19 general statement, but as to surgical site infections, the
20 only thing anyone has ever relied on is the Kurz and Sessler
21 study which the authors themselves say doesn't pass muster.

22 THE COURT: So page 170 of that deposition, 179?

23 MS. CONLIN: 179, lines 16 through 19. And the
24 final point I forgot to make when I was up the first time
25 but -- and I didn't talk about it because I don't think it

1 moves the needle one or the another is that 2017 Augustine
2 study which there isn't any author in it other than Scott
3 Augustine, and for the reasons Mr. Ciresi suggested, we
4 haven't had a chance to question him yet, but we are very
5 much looking forward to it.

6 Dr. Samet didn't cite that in his report. He
7 didn't cite it in his supplemental documents --

8 MAGISTRATE JUDGE NOEL: I thought Dr. Samet which
9 is why Mr. Blackwell told me --

10 MS. CONLIN: He mentioned it in passing in his
11 deposition because the study had just come out, but we
12 didn't file a supplemental report saying Dr. Samet is
13 relying on. He said, you know, in his deposition, one of
14 the reasons he never filed a supplemental report is, unlike
15 McGovern where he kicked the tires, he hadn't kicked the
16 tires on Augustine. It just had come out, and there was
17 material coming in, so there is no expert --

18 MAGISTRATE JUDGE NOEL: Just to follow up on the
19 question I asked Mr. Blackwell. My recollection of the
20 argument in one of the prior motions was that the Augustine
21 2017 article was simply not going to be a thing in this
22 trial. Is it still the plaintiffs' position that that's not
23 a thing?

24 MS. CONLIN: Yeah, we are relying on our experts
25 reports as filed and they do not -- Samet does not include

1 Augustine as a point of reference.

2 MAGISTRATE JUDGE NOEL: Okay.

3 MR. BLACKWELL: Can I clarify just one point?

4 THE COURT: Could you just give me one second?

5 MAGISTRATE JUDGE NOEL: We're never going to get
6 to -- as I understand it, we're still on, like, the first
7 group of motions, and it's almost 3 clock.

8 THE COURT: We can solve that by not looking at
9 the clock.

10 Epidemiology, can you just talk to me a little bit
11 about that science?

12 MS. CONLIN: Sure.

13 THE COURT: I have the overall impression that an
14 epidemiologist looks at risk in -- against a -- like the
15 background risk, you've got people who are at risk of
16 something and then you introduce something and does that
17 increase the chances that there's going to be a negative
18 outcome?

19 MS. CONLIN: Yeah.

20 THE COURT: But I don't have the impression that
21 what an epidemiologist does is say, look, we've got two
22 products and I'm going to evaluate one against the other and
23 I'm going to say you ought to use this one instead of that
24 one, so is that epidemiology or is epidemiology saying this
25 will increase, this will increase, or do you know what I

1 mean?

2 MS. CONLIN: So broadly speaking, an
3 epidemiological study is comparing two groups, so if you
4 take, for example, the McGovern group, one got HotDog, one
5 got Bair Hugger, or the Darouiche study where one was just a
6 patient undergoing surgery and the second group where there
7 was a HEPA air barrier blowing across the surgical site to
8 ensure that no particles came in, and what they do is they
9 rely on observational studies such as --

10 THE COURT: But Darouiche is different. I think
11 McGovern from an -- so you think McGovern as comparing --
12 they're comparing two commercial products.

13 MS. CONLIN: Yep.

14 THE COURT: And they're saying one we think is
15 better than the other.

16 MS. CONLIN: No.

17 THE COURT: Is that epidemiology?

18 MS. CONLIN: They're comparing two sets of
19 patients, and that's the difference. The epidemiologists
20 aren't typically saying, you know, this is the product that
21 use or whatever, but what they're doing is comparing two
22 groups of individual and they are determining whether the
23 changes between the two groups effect health outcomes.

24 THE COURT: Right. But it's usually a group -- it
25 would be, for example, the HotDog group versus infections

1 generally or the Bair Hugger versus the infections
2 generally, right? Not saying yet a compared, you know a
3 Bair Hugger to a --

4 MS. CONLIN: To nothing?

5 THE COURT: Right.

6 MS. CONLIN: Yeah, so I can put Your Honor's mind
7 at ease on that because both Doctors Borak, their
8 epidemiologist, and Dr. Samet, our epidemiologist, have said
9 that the central question here is, you know, between an
10 alternative forced air warming such as a blanket or
11 conductive warming or all the things that you can do keep a
12 patient warm that don't blow air versus Bair Hugger, and
13 that's in Dr. Borak's report in paragraph 11. Dr. Samet
14 said you can either compare it against someone who's not
15 warmed at all or you compare it against -- the Bair Hugger
16 against someone who's not warmed at all or you can compare
17 the Bair Hugger against somebody who uses an alternative
18 warming modality such as HotDog. So there isn't actually
19 really any dispute between the experts in this case on that,
20 and their expert has said that the inquiry that was looked
21 at in McGovern is the appropriate way to look at it.

22 THE COURT: Okay. All right. Thank you.

23 All right. I apologize, Mr. Blackwell. You were
24 about to get up when I said hold on.

25 MR. BLACKWELL: Permission from Judge Noel, I'll

1 be very, very -- I understand. Very brief. I just wanted
2 to show you all, Your Honors, the actual quote from Dr.
3 Kurz since that was just referred to by counsel where
4 Dr. Kurz supposedly said something about there being no
5 benefit to normothermia. And the one thing I know all of us
6 know was what the full examination was. And you see where
7 the question starts at line 14, And earlier I think there
8 were some questions about some comments that had been made
9 either by you or Dr. Sessler that maybe effect size would be
10 only 30 percent. Do you recall those? Yes, I do that
11 recall all. I understand that's just your best judgment,
12 blah, blah.

13 So I want to make it clear you're not saying or
14 are you saying that evidence that no longer supports the
15 idea that make this normothermia reduces the risk of
16 surgical site infections? I think if I understand you
17 correctly, I'm not saying that. I am saying that I believe
18 maintenance of normothermia decreases infection risk but the
19 effect size might be closer to 30 percent reduction or so
20 which, in effect, is enormously large effect size for any
21 medical intervention.

22 So it is quite the opposite of saying there is no
23 benefit. And I once again, I just want the record to be
24 clear about what the testimony really is from Dr. Kurz. So
25 thank you, Your Honor.

1 THE COURT: You know, the exhibit only goes to
2 page 180, at least the one I found, but so we must have a
3 page 200 someplace else.

4 MS. CONLIN: No.

5 MR. BLACKWELL: Looking here, so Mr. Hulse is.

6 MR. HULSE: It's definitely docket 213-2. May
7 have it some other place as well.

8 THE COURT: Okay. But it's in here somewhere.

9 MR. BLACKWELL: It's a fulsome treatment. Thank
10 you, Your Honor.

11 THE COURT: Thank you. So, now, where are we?
12 Plaintiffs motions to exclude Borak and Holford.
13 Mr. Sacchet.

14 MR. GORDON: Your Honor, can I indulge the Court
15 for just a very brief bathroom break?

16 THE COURT: Maybe it's time for a break. We'll
17 take a break. We're in recess.

18 (Recess taken from 2:54 p.m. until 3:11 p.m.)

19 (3:11 p.m.)

20

21 THE COURT: Please be seated. Mr. Sacchet.

22 MR. SACCHET: Good afternoon, Your Honors.
23 Michael Sacchet on behalf of all plaintiffs moving to
24 exclude Professor Holford and Dr. Borak.

25 Before I delve into the merits of each respective

1 motion, I would like to make a few preliminary comments. My
2 intention is to first address the issues with Dr. Holford's
3 report and then to transition to Dr. Borak. The reason
4 being is because Dr. Borak in large part relies on the same
5 analysis that Professor Holford conducted in his report. So
6 my analysis of Dr. Borak's testimony will be much briefer
7 than it will be as to Dr. Holford. However, I promise that
8 the time will be made up with respect to Dr. Borak.

9 I'd also like to be candid with the Court. When I
10 first reviewed 3M's expert disclosures, I was indeed
11 impressed with their respective backgrounds of Professor
12 Holford and Dr. Borak. They both teach at Yale. They
13 published articles in national journals, and they teach
14 extremely bright students. At the same time, within just a
15 few minutes of reviewing both of their reports, there were a
16 number of issues that stuck out immediately in comparison to
17 Dr. Samet's report and the other expert reports that
18 plaintiffs have proffered in this litigation. And there are
19 four threshold issues that I'm going to identify first.

20 The first is that unlike Dr. Samet, it is
21 undisputed that Professor Holford relied on 19 sources of
22 evidence, which are in full cited on page 14 of his report,
23 and at his deposition, he admitted numerous times over that
24 he conducted absolutely no independent review of the exigent
25 evidence in this case or in the scientific literature

1 outside of the 19 documents that were provided to him by 3M.
2 That is certainly not the case with respect to Dr. Samet who
3 outlined in his report a comprehensive search of the
4 scientific literature, which in the end amounted to nearly
5 200 sources of evidence that he considered in rendering his
6 opinion as to causation.

7 Numerous courts have concluded across the country
8 that when an expert is spoon fed information in the same
9 manner that Dr. Holford has been spoon fed here, that that
10 shows an improper methodology under Daubert. We have cited
11 those cases in our papers but one in specific is *In Re TMI*
12 out of the Third Circuit. It's a comprehensive decision. I
13 believe it spans over 75 pages long, but as to numerous
14 experts the Court made that very same determination and
15 excluded experts on those grounds.

16 The second contrast to Dr. Samet is that
17 Dr. Holford, and I'll explain a lot about this later, relied
18 on Exhibit 10 as opposed to the final raw data published in
19 Figure 7. And I understand that the Court is already aware
20 of that, and I will explain it in more detail as I progress
21 in the argument. What I do want to make clear off the bat
22 is that courts also routinely exclude expert witnesses that
23 attempt to reanalyze, not just analyze, but reanalyze data
24 that is published in peer-reviewed studies and do so based
25 on incomplete or unreliable or inadequate information.

1 In fact, *In Re Baycol*, which was in this district,
2 Judge Davis did just that and excluded an expert for that
3 very reason.

4 JUDGE LEARY: How is that different than what the
5 plaintiffs' arguments have been with regard to the science
6 cited by the defendants?

7 MR. SACCHET: Could you?

8 JUDGE LEARY: How is the statement that you made
9 any different than the type of challenges that the
10 plaintiffs' counsel have made to challenge the defense
11 evidence, scientific evidence?

12 MR. SACCHET: The primary difference, Judge Leary,
13 is, of course, peer-reviewed scientific literature as a
14 minimum indicia of reliability. Numerous courts have stated
15 that over and over again. Daubert too, for example, out of
16 the Ninth Circuit said that if an article is published in
17 the scientifically peer reviewed literature that it at least
18 meets the minimum criteria of reliability.

19 And of course, one can attempt to poke holes in
20 that literature and demonstrate that there may or may not be
21 flaws, but as a threshold matter, experts routinely rely on
22 what's published in the study. After all it has peer
23 reviewed and has been accepted and in this case The Journal
24 of Bone and Joint Science is a preeminent scientific journal
25 on the particular subject matter of this litigation, which

1 is orthopedics.

2 So it is our view that in any form Dr. Samet had
3 all the right to rely on not just what was published in the
4 McGovern study, but on Figure 7. And I would like to make
5 this point clear right now, and I was going to save it for
6 later, but many scientific studies do not include something
7 of the sort like Figure 7. What they generally include is
8 what is Table 2, which is also in the McGovern study.

9 And in Table 2, what is reported there are simply
10 the figures that were compiled based on the underlying data,
11 but there is no representation in the normal course of
12 scientific literature as to a graph containing jitter data
13 points as was included in the McGovern study. So that is a
14 factor that distinguishes the McGovern study from many other
15 studies that don't even attempt to depict the underlying
16 data. I hope that answered your question.

17 JUDGE LEARY: No, I'm not sure that you have.
18 You're saying it's not proper for a party's expert to recast
19 the reports of an expert, and yet your colleagues have done
20 that with regard to the report cited by the defense. How do
21 you distinguish?

22 MR. SACCHET: So the main distinguishing feature
23 is that it is our argument that Dr. Holford relied on a
24 flawed data set in attempting to retabulate the data.

25 THE COURT: So you're saying it's okay to go ahead

1 and use the data from somebody else's study and come up with
2 a different conclusion as long as you do it right.

3 MR. SACCHET: I think that happens in tons of
4 litigations. Experts analyze data and if they're relying on
5 appropriate data to reanalyze that data perhaps using a
6 different test or looking at it in a different way that's
7 one thing. But here my argument as I progress this
8 afternoon is to show that that is not what Professor
9 Holford. He did not in fact rely on a reliable source, and
10 I have excerpts of deposition testimony where he admits as
11 much.

12 JUDGE LEARY: Go ahead.

13 MR. SACCHET: The third contrast with respect to
14 Professor Holford's testimony and Dr. Samet's testimony, and
15 this also applies to Dr. Borak as well, and this has been a
16 topic that's been discussed already a bit ad nauseum here
17 this afternoon is the difference between DGI and SSI. It is
18 undisputed that Professor Holford and Dr. Borak admitted
19 under oath that they are not one in the same.

20 Moreover, they admitted that it was improper as a
21 scientific matter to conflate one with the other. And the
22 explanation is simple, they have vastly different
23 ideologies. A surgical site infection requires hundreds if
24 not thousands of bacteria to create an infection because the
25 body naturally has a host defense that can cleanse those

1 areas of the infection.

2 But with respect to a deep joint infection on a
3 prosthetic implant, there is no blood circulation. Biofilm
4 can form right over the bacteria area, a very small
5 inoculum, and protect it from antibiotics and other
6 medications that would otherwise be used in other types of
7 surgery. So the proposition that these are the same thing
8 is belied by the very expert reports that 3M has submitted
9 in this litigation.

10 I don't want to get back into the FDA document,
11 but the same reasoning applies, and it's my view and it
12 stands to reason that the FDA letter specifically used the
13 language SSI. I understand that it arose out of concerns
14 perhaps due to orthopedic infection. But at the same time,
15 when the FDA citing studies that purportedly show that the
16 use of intraoperative warming reduces the risk of surgical
17 site infection, there's not a single published study, none,
18 that show intraoperative warming reduces the risk of deep
19 joint infection, which is the outcome of interest in this
20 litigation.

21 But, nonetheless, Dr. Borak throughout his report
22 conflates those terms, and he reveals as much in language
23 such as to the extent that this purported hypothetical
24 confounding variable impacts DGI, only then or in that case,
25 it is a confounder. Never says that it is, only says if

1 this SSI measure impacts DGI in that case there's a
2 confounder. That's not a conclusion. That's speculation
3 and should be excluded.

4 The fourth difference between Dr. Samet and
5 Professor Holford and Dr. Borak is that they attempt to
6 opine on general causation but at the same time all that
7 they have done is critique a single study. That is not the
8 practice of epidemiology as The Scientific Reference Manual
9 makes clear. Causation is a judgment informed by scientific
10 expertise based on multiple lines of evidence. And I do not
11 know how methodology could be sound when one is attempting
12 to opine on general causation based on 19 sources of
13 evidence that 3M provided to that expert. That is just not
14 the totality of evidence.

15 We included numerous admissions from both of these
16 experts in our papers. None of them have been disputed. 3M
17 has responded to virtually none of them. They're sitting
18 there on the paper apparently uncontested. What 3M did
19 instead is violate Rule 703. They've cited more than ten,
20 perhaps even 20 documents in their opposition papers to our
21 motions to exclude Professor Holford and Dr. Borak that were
22 never acknowledged, cited, mentioned by either one of those
23 two experts. That filling a brief is improper, and none of
24 those exhibits can rehabilitate the admission that both of
25 those experts gave us at their depositions.

1 In my view, what that showcases is one thing and
2 one thing alone, their testimony is unreliable and there's
3 an ex post facto attempt to rehabilitate them after the time
4 in which they could have done so, so none of those exhibits
5 should be excluded, and I'm happy to enumerate them and I'll
6 just enumerate the most basic examples: DX6, DX7, DX8,
7 DX11, DX19, DX20, DX21, DX34, docket 231 --

8 COURT REPORTER: I'm sorry, I lost you at DX21.
9 Repeat it please.

10 MR. SACCHET: DX21 -- and actually I appreciate
11 the interruption because DX21 is like the most ripe example
12 that I could possibly bring up. Dr. Holford admitted at his
13 deposition that he didn't rely on a single study to show
14 that an antithrombotic can confound deep joint infection,
15 not a single one.

16 Now, four months after I took his deposition, 3M
17 has ginned up a study by Brimmo et al from 2016 that
18 purportedly shows that a use of an antithrombotic increases
19 the risk of infection. I'm going to get into it in more
20 detail, but not only is it improper under Rule 703, but it
21 doesn't even move the needle because it's not the same
22 regimen that was used in the McGovern study. Although, it
23 involved Rivoraxaban, but it did not involve Tinzaparin. It
24 involves a completely different antithrombotic. And the
25 *Glastetter* court made clear that when you evaluate

1 confounding, even the smallest difference in the molecular
2 structure can determine whether or not a variable is a
3 confounder, so even that inadmissible evidence does not save
4 Holford's opinion as to confounding.

5 With respect to Plaintiff's particular motion --

6 Oh, so other exhibits, excuse me, I ended at DX21,
7 DX34 is an internal document from 3M, docket number 231 and,
8 the May 18, 2017 hearing transcript. In addition to that,
9 there are numerous excerpts of deposition testimony and
10 other exhibits that were shown at those depositions that I
11 do not believe the experts have reviewed and those include
12 DX9, DX10, DX12, DX17, DX25, DX26, DX28, DX31.

13 As to Professor Holford in particular, plaintiffs
14 have moved to exclude his testimony in its entirety, and we
15 have identified seven particular topics of testimony. It is
16 plaintiffs' view that the first four topics of testimony 3M
17 has failed to respond to and are, therefore, waived and they
18 should be excluded on that basis alone. Those include
19 Professor Holford's use of competing statistical tests, his
20 opinions about comparing hospital infection rates and time
21 trend data, potential confounders from SSI measures, and his
22 opinions about general causation. 3M has responded to our
23 arguments regarding reclassification of patient data, the
24 new start date, and the potential confounding from the
25 change in antibiotic and antithrombotic, and I would like to

1 move through those seven topics going quite briefly through
2 the first four because 3M has not responded to them and
3 emphasizing the last three as I finish the first four.

4 The first topic is Professor Holford's
5 flip-flopping, if you will, with respect to statistical
6 tests throughout his report. I'm going to back up for a
7 moment and, hopefully, enlighten the Court that the authors
8 of the McGovern study used a statistical test called
9 chi-square. It's a commonly used test. I learned it in
10 college in my Statistics 101 class. It's used in a lot of
11 studies. And in fact, Professor Holford uses it probably
12 more than not in most of his studies, and he also used it in
13 particular circumstances that are exactly the same as the
14 McGovern study but for some unknown reason he chose not to
15 do so here.

16 Instead of applying chi-square, Professor Holford
17 uses a test called Fisher's exact test. And Fisher's exact
18 test has been criticized by numerous statisticians and
19 academics across the country. When I deposed Professor
20 Holford, he recognized as much because in general it can
21 change a statistically significant value to a
22 non-significant value. Now all of this is more or less
23 besides the point because whether or not there is a
24 statistically significant association to the McGovern study
25 or whether it's just below or above statistical significance

1 should not be determined -- the determination by which the
2 Court adjudges the McGovern study. But I would like to
3 point out why I believe that Professor Holford's testimony
4 is litigation driven.

5 There are two rules that statisticians consider in
6 determining whether to apply chi-square as the McGovern
7 authors did versus Fisher's test, which is the test that
8 Professor Holford used, and he used it in order to change
9 the P value.

10 The first rule is if the population of the study
11 participants exceeds one thousand, you should use
12 chi-squared. There is no dispute that the McGovern study
13 had one 1,437 patients. Obviously, satisfying that
14 criteria.

15 The second criteria are expected values as opposed
16 to reserved values greater than five. And I don't want to
17 wade too far into the weeds, but the statistics show that
18 expected values would be greater than five in which case you
19 should apply chi-squared.

20 When I asked Professor Holford why didn't you
21 apply chi-square when the expected values are greater than
22 five? This is what he said. I asked, him, "So based on
23 your own bias, you relied on the actual values reported in
24 the study itself as opposed to the expected values that most
25 statisticians rely on to determine whether to apply Fisher

1 or not." "Yeah. That's probably less commonly used on
2 observed values, but I prefer to do that because I think in
3 this case actually the expected values are greater I believe
4 than the nominal five, if that's the rule you're using."

5 So Professor Holford not only admitted that he
6 decided to use Fisher's test instead of chi-squared based on
7 his own bias, but he also admitted that the expected values
8 were greater than five, which counsel it must apply
9 chi-squared. I believe that this excerpt testimony alone
10 shows that Professor Holford's decision to use Fisher's test
11 instead of chi-squared depended on his own bias, which is
12 not reliable and is not a valid methodology by which he
13 attempted to reanalyze the data in the McGovern study.

14 I will also mention that *In Re Lipitor*, which
15 Mr. Blackwell in his opening argument said it was a
16 wonderful case that is on all fours with this case. I
17 agree. In that case, they excluded the expert because he
18 flip flopped between different tests just as Dr. Holford did
19 in his report. At the beginning of his test, he applied
20 Fisher's test and then just as Mr. Gordon admitted in his
21 argument, then he suddenly switched to chi-square. I would
22 argue that he did so to manipulate the results so he could
23 achieve the desired result.

24 The second topic of testimony that 3M has not
25 responded to in its opposition is Professor Holford's

1 testimony regarding hospital infection rates and time
2 trends. The background of this argument is that in the
3 McGovern study, the rate of infection among the Bair Hugger
4 group was three percent. Dr. Holford determined that that
5 rate is out of control, and he got there based on reviewing
6 data from other hospitals that purportedly showed a rate of
7 infection of 0.6 percent.

8 Now, I was struck by this argument when I read it
9 because the first thing I noticed when I was preparing for
10 the deposition is Dr. Holford didn't compare apples to
11 apples. We keep hearing about apples to apples, But that's
12 not what he with did. He compared apples to oranges. He
13 evaluated the 2008 to 2010 period for the Bair Hugger, to a
14 2010 to 2015 period among other hospitals that may or may
15 not have used conductive fabric warming devices instead of
16 the Bair Hugger.

17 I would argue that to the extent that there was a
18 decreased risk of DGI or rate of DGI, that it perhaps
19 aligned exactly with the McGovern study, and the use of
20 conductive fabric warming devices instead of the Bair Hugger
21 device is what caused the decrease.

22 The third issue is that Dr. Reed, who is one of
23 the primary authors of the McGovern study swore under oath
24 that the hospitals in the UK are notorious for under
25 reporting data and that one could not rely on rates reported

1 by other hospitals such as the very ones that Dr. Holford
2 relied on in performing his analysis.

3 Now, outside the courtroom, Dr. Holford has
4 published numerous articles explaining you must rely on
5 complete data, otherwise the analysis will suffer from data
6 artifact. It's exactly what he did here, and here's another
7 exhibit to prove that.

8 When I was cross examining him on this very
9 question, I said Dr. Holford, do you know the degree of
10 accuracy of the calculations by which you're comparing the
11 Bair Hugger period to these other hospitals? "I don't know
12 the degree of accuracy. That was not part of the data that
13 I was provided as to the measure."

14 So I then asked, "and you didn't ask for the
15 data?" "No." So I said, "To the extent you argued that the
16 infection from 2010 to 2015 was .6 percent, are you aware
17 that there was a significant decrease in deep joint
18 infections in the NHS from 2013 to 2015?"

19 "I didn't have data specifically relating to
20 these." I think this excerpt alone shows that Professor
21 Holford did not use reliable methodology in comparing
22 hospital infection rates. 3M has not responded to that
23 argument either.

24 The third topic that 3M has not responded to is
25 hypothetical confounding from SSI measures. Throughout

1 Dr. Holford's report, he cursorily states, yeah, SSI
2 measures may have confounded the McGovern study, and they
3 should have been controlled because had they not been, that
4 could have resulted in the increased risk of infection that
5 was reported therein.

6 What he told me at his deposition is that he
7 didn't study the impact of surgical site infections on deep
8 joint infection. That's at page 367. Surgical site
9 infections are not the same as deep joint infections.
10 That's at page 304. He does not have expertise to evaluate
11 the relationship between deep joint infections and surgical
12 site infections, and at bottom he had no scientific basis
13 whatsoever to testify that surgical site infection
14 interventions may have confounded the DGI rate. And here's
15 the admission where he says as much.

16 I asked him, "your report concludes that the SSI
17 bundle may have had an effect on deep joint infection rates,
18 correct?" "Yes, the things that they were doing to control
19 SSI may have had an effect."

20 So I said, "You have no scientific basis to make
21 that conclusion." Answer, "I'm -- no, no, I'm just assuming
22 that it does." This is ipse dixit.

23 The fourth topic of testimony that 3M has not
24 responded to in our papers deals with Professor Holford's
25 general causation findings. As I mentioned at the outset,

1 epidemiology is the practice of considering multiple lines
2 of evidence and the totality of evidence. Professor Holford
3 did not do that. Instead he only offered statistical
4 evaluation based on the McGovern study, and he did not go
5 beyond his biostatistical analysis.

6 And in this slide, we went through that. In the
7 very beginning of the deposition, I asked him, "Are you
8 offering testimony as to any of the subject matters," that I
9 had previously went through with him, and he said, "I'm
10 offering testimony on statistical aspects that relate to the
11 Bair Hugger. I don't know if you think that's relevant or
12 not."

13 So I sat on that, and I waited until the end of
14 the deposition, and then I circled back and I said, "Do you
15 agree with the statement from The Reference Manual on
16 statistics that in the end deciding whether associations are
17 causal typically is not a matter of statistics alone but
18 also rests on scientific judgment?" Answer, "Yes."

19 I believe that slide in and of itself shows that
20 Dr. Holford did not consider more than statistics when he
21 opined that the Bair Hugger was not a substantially
22 contributing cause of deep joint infections and, therefore,
23 he should be excluded from rendering these opinions in this
24 matter.

25 I would also like to point out that with respect

1 to Dr. Holford's testimony at his deposition as opposed to
2 what he wrote in his report, he actually corroborated
3 Dr. Samet's opinions about general causation. On the
4 record, Professor Holford admitted that temporality was
5 satisfied. He also admitted that temporality is the only
6 prerequisite under the Bradford Hill criteria by which must
7 be met in order to show causation, and he said that was
8 readily satisfied here. And as my colleague Ms. Conlin
9 pointed out, Dr. Borak made the same assertion.

10 The second point, and this has been alluded to
11 throughout argument today. Professor Holford also said even
12 an odds ratio less than 2.0 can be sufficient to show
13 causation. That's important. Because even if for the sake
14 of argument, which I don't think is right, that the McGovern
15 3.8 odds ratio is not correct. Even if it's above 1.0, one
16 can still rely on that to show causation. That's what he
17 admitted on the record.

18 He also admitted on the record that when an odds
19 ratio is above 2.0, that you can rely on that to show
20 specific causation in a similarly situated individual.
21 That's not only met here based on the risk ratio reported by
22 McGovern, but even if you use Fisher's test, which is what
23 Holford did. And even if you assumed that there is one less
24 Bair Hugger infection and one more HotDog infection, the
25 odds ratio is still 2.76, which is above the threshold by

1 which Professor Holford admitted we could prove specific
2 causation.

3 He also admitted that consistency was satisfied,
4 which is the third factor under the Bradford Hill criteria,
5 and he said that in some cases one can assume a relationship
6 between particles and bacteria; therefore, agreeing with the
7 chain of infection that plaintiffs have presented in this
8 litigation throughout today's argument.

9 The fourth thing he admitted was that studies can
10 show coherency if they are mechanistic. And, moreover, that
11 all of the concern as of late with respect to water heater
12 cooler devices and the FDA recall that has ensued involved
13 or coincide the same concern with respect to the Bair
14 Hugger.

15 I'd like to now jump into the three topics of
16 testimony that 3M has responded into their papers. And the
17 first is, obviously, the hot topic of the reanalysis of the
18 McGovern study. As background information, and I know
19 Mr. Gordon has made this clear, and so has Ms. Conlin, but
20 it bears repeating, the published study reported 32 out of
21 1066 patients incurred a deep joint infection during the
22 Bair Hugger period.

23 On the other hand, there were three reported
24 HotDog infections out of a population of approximately 371.
25 Instead of using that data, Dr. Holford opines that in fact

1 there were 31 Bair Hugger infections, one less than the 32,
2 and there were four HotDog infections instead of the three
3 that are reported in the study.

4 Figure 7, which is reflected here and has also
5 been brought up this afternoon, and I'm happy to answer
6 questions about it, but, again, the legend of that graph
7 states that it is the raw case data underlying the numbers
8 in Figure 2 of the study, the particular data points are
9 reflected therein in both arms of the study. But instead of
10 relying on that information, Professor Holford relied on
11 what's been known as Albrecht Exhibit 10. I'd like to be
12 clear that Albrecht Exhibit 10 was not produced by
13 Mr. Albrecht. It was not produced by any of the study
14 authors.

15 I also want to make clear that Exhibit 10 is kind
16 of a statistical matter, is not even machine readable. When
17 you do statistical analysis, you generally do it based on a
18 CSV file, which is a common separate eval file. The three
19 or four hundred page document that is so-called Exhibit 10
20 is not that and would not be able to be plugged in and
21 generate data based on that fact.

22 Before I critique Professor Holford testimony on
23 this point, I want to go back to the idea let's assume that
24 there was one less Bair Hugger infection, and let's assume
25 that there was one more HotDog infection, if we make that

1 assumption, Professor Holford's report states on page 3 that
2 there would still be nearing a tripling of the risk, an odds
3 ratio of 2.76, and that the P value, even though we dispute
4 that statistical significance matters much, is still
5 significant at 0.048 below the conventional threshold of
6 .05. That's based on Professor Holford's own analysis.

7 If you apply Fisher's test, which is what he did,
8 the odds ratio stays the same. It's still 2.76 above the
9 2.0 doubling of the risk threshold, and the P value instead
10 of being .04807 goes up by a few thousandths of a decimal
11 point to .0507. And based on that difference of a few
12 thousandths of a decimal point, Professor Holford says the
13 McGovern study doesn't mean anything.

14 The United States Supreme Court in the *Matrix*
15 decision in 2011 denounced that very reasoning holding that
16 medical experts do not need to rely on statistically
17 significant data in order to opine on causation. Moreover,
18 the American Statistical Association came up with guidelines
19 in 2017 that said bright lines should not be drawn based on
20 conventional standards of statistical significance because
21 to do so would invite unreliable conclusions. That's
22 exactly what Professor Holford opines here.

23 Moreover, Dr. Samet at his deposition, yeah, they
24 asked him what if there was one more or one less? Dr.
25 Samet's response, it wouldn't change my view. You still

1 have almost a tripling of the risk. You still have
2 significance, whether it's clinical or statistical. It
3 stands of its own weight.

4 Dr. Reed, one of the primary authors of the
5 McGovern study, same exact testimony from him. And this is
6 what I want to emphasize. We've heard probably an hour or
7 two of argument about this particular issue. 3M has
8 predicated its expert reports on the existence of one more
9 or one less infection. They're now up here arguing we can't
10 prove causation as a result. Let's look at what they told
11 Mr. Albrecht. My friend on the other side during that
12 deposition asked Mr. Albrecht a few questions about it. And
13 then this is what he said:

14 "I don't want to focus too much on the difference
15 between 31 and 32 and 3 and 4, because I don't think this is
16 a good use of time at this point." "Okay."

17 So the very point of all of this argument today
18 was expressly essentially said to be a waste of time at
19 Mr. Albrecht's deposition. It really doesn't add up in my
20 view, and I think this excerpt proves that point.

21 Notwithstanding the fact that 3M and its attorneys have
22 admitted that it's an immaterial distinction, Professor
23 Holford's reliance on it is fatally flawed for a number of
24 reasons.

25 The first is that he had no foundation whatsoever

1 to believe that Exhibit 10 is the final data. And, Judge
2 Leary, that's where I distinguish reanalysis of published
3 data based on accurate data from reanalysis based on
4 inaccurate or incomplete data.

5 When I deposed Professor Holford, this is the
6 colloquy that ensued.

7 I said, "Mr. Gordon," which is 3M's counsel,
8 "doesn't know if Exhibit 10 is the original data set."

9 His answer: "Okay."

10 I then asked, "Mr. Albrecht also doesn't know
11 whether Exhibit 10 is the original data set." "Yeah."

12 "Mr. Borak," the other epidemiologist at 3M has
13 disclosed in this litigation, "also doesn't know whether
14 Exhibit 10 is the original data set."

15 "Okay."

16 "And you don't know."

17 "Answer: I don't."

18 I don't know how a statistician can't opine that a
19 peer reviewed study is fatally flawed when he doesn't even
20 know if it's the final data set. That is the quintessence
21 of unreliability under Rule 702 and 703, and he should be
22 excluded.

23 If that were not enough, and I think it is by any
24 reasonable doubt, he also admitted on the record that
25 Exhibit 10 was incomplete. He learned for the first time at

1 the deposition that that exhibit was missing an entire page
2 of deep joint infection data during the Bair Hugger period.
3 He didn't know that before because he admitted to me that he
4 didn't go through by hand the exhibit. He didn't go through
5 the tabulation by hand. He didn't review it. He just
6 relied on what 3M gave him, and this is what he told me:

7 "I didn't see that there was a missing page in the
8 data set that I used to analyze."

9 Under this Court's Order *In Re Baycol*, he should
10 be excluded based on these two admissions alone.

11 The last thing I would like to mention is when I
12 examined Dr. Holford, I put Figure 7 side by side with
13 Exhibit 10 in McGovern Exhibit 16, which is the very
14 document that Mr. Gordon, my friend on the other side,
15 presented to you this afternoon, to have allegedly assumed
16 that one of the infections was miscoded as forced air
17 warming instead of conductive fabric warming.

18 When I showed Professor Holford Figure 7 side by
19 side with the data set that underlies that published
20 manuscript number 10, Professor Holford admitted on the
21 record that Exhibit 10 was missing a data point that is
22 reflected in Figure 7 of the McGovern study, specifically in
23 September of 2008. He admitted that on the record.

24 Dr. Holford also admitted on the record that he
25 did not analyze data that the McGovern authors collected

1 after publication of the study so you heard a lot of
2 allegations by 3M that the McGovern studies or the McGovern
3 authors may have intentionally chosen this particular data
4 or this particular day to achieve statistical significance.
5 Unfortunately, the McGovern authors collected six more
6 months of data after the end of the McGovern study doubling
7 the size of the population of the HotDog group from
8 approximately 371 patients to around 700 patients or 800
9 patients.

10 The same exact results. Statistically
11 significant, even though we did not depend on that, and all
12 show the ratio of 3.6; albeit a .2 decrease in the odds risk
13 ratio, almost a quadrupling of the risk based on an expanded
14 data set that Dr. Holford admitted at his deposition
15 contradicted his analysis in this case.

16 Dr. Holford also did not review the deposition
17 testimony of the authors who plainly testified that they did
18 not know whether Exhibit 10 was the final data set based on
19 a mere showing of this 300 page document. Not a single
20 author in this case has said that Exhibit 10 is the final
21 data set. No one. Not Mr. Albrecht, not Mr. McGovern, not
22 Dr. Reed, not Dr. Belani, and not Professor Nachtsheim.
23 None of them have said that Exhibit 10 is the final data
24 set. And that is what 3M has hung its hat on in this case
25 to show the purported invalidity of the McGovern study even

1 though if you add infection or take one away, there's still
2 a 2.76 odds ratio.

3 JUDGE LEARY: Somebody mentioned something that
4 maybe has been bothering me a little bit in terms of the
5 comments that you've made, Counsel. The original challenge
6 to McGovern was whether or not, whether that study was
7 scientifically reliable, and in effect whether or not it was
8 properly motivated, and at issue was Augustine and
9 Albrecht's involvement in that study. And certainly there
10 were internal communications between Augustine and Albrecht
11 that questioned the purpose, the motivation under which that
12 study was undertaken.

13 And I'll draw up, you know, language from criminal
14 case law, where you talk about the fruit of the poisonous
15 tree. And when you see a motivation like Augustine's, and
16 you see the internal communications between Augustine and
17 Albrecht, and then you see some change in the way
18 information is graphed, and some change in the statistics,
19 you begin to wonder about the overall validity and the
20 motivation of the study. What you're now suggesting is to
21 bootstrap, if you will, the integrity of that by in effect
22 recasting it and trying to undercut the opinions that
23 Holford holds as a way of legitimizing McGovern. But still
24 in the first instance in terms of assessing scientific
25 reliability, the motivation behind that study, and the

1 desire for a certain outcome, I think you just can't will
2 that away from questioning the analysis by Holford, because
3 they're two different things. And when somebody approaches
4 a scientific study with a lack of objectivity, I don't think
5 you ever move away and certainly perhaps not in this
6 particular study from that motivation, regardless of how a
7 party wishes to undercut somebody else's analysis of that
8 information. And that's what troubles me.

9 MR. SACCHET: If I could briefly respond. So this
10 is the first point is not in answer to your question, but I
11 do want to make it clear that for purposes of the motion to
12 exclude Holford, he did not rely on the documents that were
13 put up earlier this afternoon that purport to show any such
14 type of motivation. So I just want to note that for the
15 purposes of excluding Holford.

16 Now as the real question and the real, answer this
17 is my response. I haven't seen a document that's been
18 produced that is specific to the McGovern study that has any
19 such suggestion about improper motive for conducting that
20 study.

21 JUDGE LEARY: Well, how about the internal
22 communication between Augustine and Albrecht?

23 MR. SACCHET: I have not seen a document this
24 afternoon that suggests that that is particular to the
25 McGovern study itself.

1 THE COURT: It was this morning.

2 MR. SACCHET: This morning, I apologize.

3 THE COURT: We saw it this morning.

4 MR. SACCHET: I believe the date of that e-mail
5 was after the McGovern study was published.

6 THE COURT: Before it was published.

7 MR. SACCHET: Before it was published.

8 THE COURT: The e-mail said we've achieved
9 statistical significance and that was all before it was
10 published.

11 MR. SACCHET: So that particular e-mail, the next
12 e-mail line beneath that is a statement from Dr. Reed in
13 which he says I have no doubt that if we continue to collect
14 data, it will show the same results. That it's not
15 necessarily a panacea for that statement between Albrecht
16 and perhaps it was with Augustine. But what I will note is
17 that the McGovern authors are some of the most well
18 credentialed people in academics around.

19 I mean Mr. Albrecht was to be sure part of that
20 study. Who is his supervisor? Professor Nachtsheim. I
21 took Professor Nachtsheim's deposition as well. He's a
22 tenured Professor at the Carlson school of Business here in
23 Minnesota. He's taught statistics for over two decades.
24 Professor Holford admitted at his deposition that Professor
25 Nachtsheim is an expert in statistics, and in fact, was

1 admitted to the college of statistics well before Professor
2 Holford. And he reviewed all of this information and
3 continues to stand behind the results of the McGovern study.

4 And so too with the other authors. Dr. Reed, one
5 of the foremost orthopedic surgeons in the UK. Dr. Belani,
6 the head of anesthesia at the University of Minnesota.
7 Dr. McGovern, I took his deposition as well. The guy could
8 not be more black and white. He would not give me a single
9 piece that I was trying to get from him. He made clear that
10 he has no doubt, he has no hesitation that there were some
11 type of fraud or manipulation of the data set.

12 So whether or not there's an e-mail saying, okay,
13 we got statistical significance, the authors still conducted
14 more analysis after the fact that show the same results, as
15 I just mentioned a few minutes ago, based on an expanded a
16 data set a statistically significant finding with the 3.6
17 odds ratio. So in my view, this whole suggestion about
18 Augustine has been and always will be a red herring. The
19 science shows what is in that study the presence or
20 difference of one or more infections does not change that
21 much the ratio or the significance of the study. And in
22 fact, as I showed even 3M's counsel didn't want to waste
23 time asking the question.

24 I would also like to note, Your Honors, that in
25 the *Viagra* case that was touched on briefly this morning, it

1 appears to be a grounds by which 3M argues that in Viagra
2 too the Court excluded a study because of data discrepancies
3 and miscoding. Two points of interest, one, the plaintiffs
4 all but failed to dispute that finding. Their arguments
5 were hollowless and the Court found as much.

6 That is the not case here where their own expert
7 is admitting that he has no basis to rely on Exhibit 10 to
8 prove a mistabulation error. Second, 11 out of the 21
9 patients in the *In Re Viagra* study were miscoded as to
10 exposure. That's nearly 50 percent. Here at best assuming
11 arguendo that there is one miscoded infection, it's one of
12 32, and it doesn't change as I keep saying the odds ratio of
13 being above 2.0 or above 1.0, which Holford agrees can still
14 shows causation.

15 That is the scope of the argument as to the
16 retabulation or reanalysis of patient data. And I would
17 like to re-emphasize again that Holford admitted on the
18 record he had no foundation to rely on it and that it is
19 missing data and, therefore, he should be excluded on that
20 grounds. Under *Baycol*, under the Supreme Court case in
21 *Watson*, which we cite, and the host of other cases in
22 footnote 2 in our reply brief.

23 The sixth topic of testimony that we have --

24 JUDGE LEARY: Let me ask you this Mr. Sacchet, you
25 know, in reviewing the depositions in this case, it's

1 represented that you talk about the integrity of the authors
2 of the McGovern article. Co-author Michael Reed was blunt
3 in his deposition, was blunt in his deposition according to
4 the defense. Asked why the authors said this, Reed replied,
5 because it doesn't. The it, the paper, doesn't establish
6 causation. And then Albrecht says the study does not
7 establish a causal basis. And that's, there's a lot of
8 confounding factors that could be at play.

9 In a communication with another research, Albrecht
10 admitted that he had admonished Augustine apparently to no
11 effect, not to overstate the studies findings. "This is one
12 of those things," this is what Albrecht says, "where we can
13 step close to the line, and we do have important information
14 to present that clinicians should be aware of, but we also
15 have to be careful that we do not state claims regarding
16 proof of infection reduction. Unfortunately, Scott
17 Augustine likes to say that he's convinced of such a
18 relationship even though I tell him it is unsupported, and I
19 do not agree."

20 Again, this was pointed out at a prior motion,
21 Albrecht finished by saying, "Well, that is the difference
22 between research and marketing."

23 So when you talk about the authors standing by
24 their conclusions and the data in McGovern, you've got Reed
25 and Albrecht saying that there's no causation here.

1 MR. SACCHET: So if I could draw a very fine line,
2 Your Honor, all of the authors stand by the increased risk
3 of the Bair Hugger, which is what is presented in the
4 McGovern study, and that is an association between the Bair
5 Hugger device and deep joint infection.

6 JUDGE LEARY: But they're saying there's no causal
7 relationship between the two.

8 MR. SACCHET: Not a single observational study of
9 any kind, not the McGovern study, not the thousands of
10 others that have been published can ipso facto prove
11 causation. It's an oxymoron. Observational studies do not
12 prove causation but associations can help show that based on
13 epidemiology and the totality of evidence. So when
14 Mr. Albrecht is discussing about what Dr. Augustine has
15 said, I wouldn't doubt that Dr. Augustine has said, yeah,
16 the McGovern study proves causation. It's wrong. That is
17 incorrect, but Mr. Albrecht is not saying that he doesn't
18 think that the McGovern study shows an --

19 JUDGE LEARY: Mr. Albrecht doesn't say what you
20 are saying he said. And Dr. Reed doesn't say that what
21 you're saying is what he said. They don't throw out those
22 distinctions.

23 MR. SACCHET: They say that the McGovern study
24 doesn't prove causation, which is exactly what I'm saying.
25 I'm saying that the McGovern study shows an association of

1 increased risk and that's what observational studies do.
2 They do not, as a matter of law or science, prove causation.
3 And not a single author of the McGovern study has ever said
4 that the McGovern study proves causation. But they do all
5 stand behind the fact that that study shows an association,
6 which is not the same as causation between the Bair Hugger
7 and deep joint infection.

8 JUDGE LEARY: I understand what you are saying.

9 MR. SACCHET: Okay. In The Scientific Reference
10 Manual, it's the opening line or the opening paragraphs of
11 the section on epidemiology. Associations don't prove
12 causation. They show a relationship, and based on that
13 relationship and other evidence, we can consider to
14 determine as a matter of scientific judgment and expertise
15 whether there is causation.

16 And the authors of this study, to be honest, Your
17 Honor, they're not epidemiologists. They didn't consider
18 the great weight of evidence. They conducted an
19 observational study. And at the end of the study, to be
20 sure, they said as they should that that study does not
21 prove causation.

22 THE COURT: What do you mean "as they should?"
23 Why do you emphasize it like that?

24 MR. SACCHET: Because no observational study
25 could. If there was any other suggestion, that would be

1 scientifically problematic.

2 THE COURT: Well, where in the study do they say
3 we find an association?

4 MR. SACCHET: Well, the P value of .0216 that is
5 reported in Table 2 of the study is below the conventional
6 line of statistical significance IE.05.

7 THE COURT: But they never say we find an
8 association.

9 MR. SACCHET: They say we find an increased risk
10 of infection of 3.8.

11 THE COURT: Where?

12 MR. SACCHET: If you look on the very first page
13 of the study in the abstract. And in fact they also do say
14 this study does not establish a causal basis for this
15 association. And that is on page 1543 beneath Figure 7 in
16 the first full paragraph, they use the word "association."

17 And as I also mentioned, the last paragraph of the
18 abstract on the first page says, "a significant increase in
19 deep joint infection as demonstrated by an elevated
20 infection odds ratio 3.8 P value .024 was identified during
21 a period when forced air warming was used compared to a
22 period when conductive fabric warming was used. Error-free
23 warming is therefore recommended over forced air warming."

24 So the authors have not only provided a risk
25 ratio, which quantifies the increased risk which we heard

1 earlier this morning, but it also says that there is an
2 association.

3 THE COURT: They're reporting what they found, and
4 they're doing a statistical analysis of what they found.

5 MR. SACCHET: Indeed.

6 THE COURT: But the sentence, they never say we
7 have and we therefore conclude that there is an association
8 between the use of the Bair Hugger. They say, I mean
9 there's nothing in here that would cause the disclaimer
10 about how we didn't have complete recordkeeping, and there
11 were other things that changed during this time period, but
12 here's we have this with it, and here's what the statistics
13 show. But a conclusion from those that there is an
14 association that can be isolated to the Bair Hugger as
15 opposed to the Bair Hugger plus all the other changes
16 doesn't appear.

17 MR. SACCHET: So my response, I don't mean to be
18 evasive, but it's generally accepted or I'll say it's
19 universally accepted in epidemiology and statistics and the
20 medical literature that if you report a P value that is
21 below the conventional line of statistical significance,
22 that shows by itself inherently an association.

23 THE COURT: Okay, but you have to look at what the
24 P value purports to demonstrate. And as they point out, the
25 P value, they don't isolate for the other confounding

1 factors incoming up with that P value.

2 MR. SACCHET: So I'm going to discuss confounding
3 factors and explain why plaintiffs do not believe that they
4 are in fact confounding factors.

5 THE COURT: I think we've been pretty well
6 educated on what your arguments are with that. But I'm
7 talking to you from a statistical standpoint when you are
8 interpreting the amount of significance to give to the P
9 value, what went into the determination that there was a
10 statistically significant difference, there were a number of
11 factors that contributed to that P value.

12 MR. SACCHET: Okay.

13 THE COURT: And so that's why I'm asking you where
14 do they say we're isolating out just the Bair Hugger. You
15 know what I'm saying?

16 MR. SACCHET: I understand now. And the answer I
17 think is what you already know, which is they did not
18 isolate those variables out in order to generate a different
19 P value. So that P value is dependent on those hypothetical
20 confounding variables not being controlled.

21 THE COURT: Right. And so there's a difference
22 between saying that there is, the association that is -- I
23 mean there is an association of the statistics are what they
24 are. But to then say that that means that they have found
25 an association between the Bair Hugger and increased

1 infection disregards the author's own statements of concern
2 about the fact that the Bair Hugger wasn't isolated in
3 coming up with that.

4 So when you say they stand by their conclusions,
5 what is that conclusion? You're putting these words about
6 the association a little bit in their mouths. I mean, it
7 does say, therefore, be cautious about using this with, you
8 know, until there's more study. The Bair Hugger was one of
9 the things that went into -- the Bair Hugger is one of the
10 factors that went into the P value, so you already know
11 about the watching to make sure that people are ready for
12 surgery and so on.

13 But one of the other things that you might want to
14 be aware of is the use of error-free patient warming
15 alternatives. And they might be recommended in an
16 environment where you need an ultra clean theater. But
17 that's not the -- I mean here's what we found there's a
18 bunch of things here, and one of them is this, so, hello,
19 study more.

20 MR. SACCHET: I understand. What I would say, and
21 I don't mean this to be a non sequitur, but all
22 observational studies may or may not have confounding
23 factors. You can't control for every particular variable.
24 It's impossible. You just can't do it. And, nonetheless,
25 courts have made clear that observational studies can be

1 relied on, and they often are relied on.

2 THE COURT: Right. And so you can have an
3 observational study, but just because observational studies
4 as almost all studies aren't going to be perfect doesn't
5 mean that every observational study comes in. I mean so
6 it's like observational studies can't be perfect, therefore,
7 ours is really, really perfect as even stated by the
8 authors, and that that you can't evaluate the level of
9 imperfection because courts have said that observational
10 studies, not all observational studies come in.

11 MR. SACCHET: I agree. What I would say in
12 response is if there are concerns on your behalf, Your
13 Honor, about particular variables that are lurking that the
14 authors alluded to as to disclosed or undisclosed potential
15 confounders that could have impacted the association, I'm
16 well versed in discussing those and explaining why in fact
17 as a scientific matter in an epidemiologic matter they are
18 not confounders.

19 THE COURT: Okay. I want to know what your
20 experts say about why doesn't -- I mean I guess I know they
21 say -- okay, what do they say about that big peak?
22 Remember, we saw the raw data just before there was a
23 change. It's the prior version of Figure 7. What do you
24 folks have to say about that big pre-March 2010 increase
25 when there was the different -- what's the P value on that

1 one?

2 What do your experts have to say about the fact
3 that there was that big, big jump, you know, that's in the
4 --

5 MR. SACCHET: Okay, the first part of my response
6 is the threshold response is one can not assume in a
7 scientific matter that DGI rates are always the same within
8 each month. I mean they can vary depending on, you know,
9 who comes in, what kind of -- is it an orthopedic surgery,
10 you know, what's going on? I mean all of these different
11 variables can change that factor so to assume that the DGI
12 rate every single day, every single week, every single month
13 of every single year is always going to be three percent,
14 doesn't make sense in my view. I mean that three percent at
15 some months could be five percent and other months could be
16 two percent and the average is three percent.

17 THE COURT: I can't remember the name of the drug
18 but there was --

19 MR. SACCHET: Rivoraxaban.

20 THE COURT: That one, so when they were using that
21 what you said, there was this peak. What do your experts
22 say about the relationship, the correlation, if any, between
23 the use of that drug you said and that peak?

24 MR. SACCHET: Okay. So the peak coincided in
25 part, not in full, but in part when the change in

1 antithrombotic regimen went from a low weight molecular
2 heparin called Tinzaparin to Rivoraxaban and then back to
3 Tinzaparin. So, in fact, the last month and a half or two
4 months of the Bair Hugger period, the patient still received
5 Tinzaparin. And that is in fact also when that spike
6 occurred.

7 But with respect to whether there was confounding,
8 and I think that's the question, there is not a single study
9 that shows that the change from Tinzaparin to Rivoraxaban,
10 the two different antithrombotics that were used in this
11 case results in an increased rate of deep joint infections.
12 There's not a single one. And as a matter of scientific
13 methodology, in order for a scientist to conclude that a
14 factor is a confounding variable, it must not only be
15 related to the independent variable, it must also be related
16 to the dependent variable. In other words, it must be an
17 independent risk factor.

18 THE COURT: And the other studies showed that
19 that's not an independent risk factor.

20 MR. SACCHET: Yeah. So there was a 2010 study by
21 Jenson and Reed. It evaluated the exact same protocol that
22 was used in the McGovern study, changed from Tinzaparin to
23 Rivoraxaban. It did not find a meaningful difference in
24 deep joint infection rates between the change in those two
25 antithrombotics.

1 After that, Reed collaborated with another
2 scientist named Jamison in 2013, a few years after
3 publication of the McGovern study. And they conducted a
4 prospective observational study evaluating the change
5 between a low weight molecular heparin very similar to
6 Tinzaparin and Rivoraxaban in 13,000 patients. The deep
7 joint infection rates are essentially identical. The P
8 value I think is .7, extremely high.

9 Based on that study, not only Dr. Reed but
10 Professor Nachtsheim, who again is a tenured professor of
11 statistics at the University of Minnesota had unequivocally
12 ruled out Rivoraxaban as a confounding factor.

13 THE COURT: So then you still have the spike, so I
14 suppose if the drugs themselves wouldn't be at how do we
15 know that there wasn't a difference in how those drugs were
16 administered? One was administered one way, one was
17 another. So if it wasn't, not it wasn't accounted for at
18 all, then the relevance of the studies that show that the
19 drugs themselves don't make a difference. I mean so your
20 experts say this is just like an anomalous jump?

21 MR. SACCHET: Our experts say that they've
22 reviewed the scientific literature, and there's not a piece
23 of evidence that suggests that antithrombotics confound DGI
24 rates.

25 THE COURT: Are they asked specifically about this

1 jump?

2 MR. SACCHET: They've seen the increase in
3 infection and do not believe that that change in rate, so --

4 THE COURT: But they couldn't have seen it because
5 this didn't get published. This is in one of the
6 previous --

7 MR. SACCHET: Well, we provided our experts with
8 many things to review. We didn't, unlike Dr. Holford, give
9 him 19 documents that were all favorable to 3M's case. We
10 actually gave our experts a very wide volume of materials.

11 THE COURT: So what does that all mean? No,
12 nobody actually talked about this jump?

13 MR. SACCHET: Well, Dr. Holford said that, yeah,
14 there's a spike in DGI rates, and that showed that rates
15 were out of control. But he does that based on splicing the
16 time period into different quarters, and then even go so far
17 as to say if you bring it down to two months, the rate of
18 infection is eight percent whereas the rate reported in the
19 McGovern study is three percent, so we can see that there
20 was a five percent increase.

21 What I would say in response to that is there's no
22 scientific methodology or proof that when you go from eight
23 percent to a two-month period or to three percent to five
24 percent in a different period that that shows that there was
25 confounding by an antithrombotic.

1 Moreover, 3M has produced a document in this very
2 litigation that we cited in our papers that was constructed
3 by their 30(b)(6) witness Mr. Al van Duren that shows that
4 the DGI rates among U.S. hospitals oscillates between 5
5 percent and 7.5 percent, which is almost exactly the same
6 percent of even that spike in the McGovern study. So to
7 suggest that there was an out of control time period in the
8 McGovern study that somehow would show up confounding is
9 belied by the very graph that 3M 30(b)(6) witness prepared
10 in this case.

11 THE COURT: Okay.

12 JUDGE LEARY: Well, then why not show the spike in
13 the graph that was published?

14 MR. SACCHET: So the authors chose to show an
15 average rate of infection as opposed to a --

16 JUDGE LEARY: Why is that any more meaningful than
17 actually showing the rate of incidents?

18 MR. SACCHET: So my view on the subject matter
19 would be in Table 2, in order to determine whether there is
20 a significant difference in infection.

21 JUDGE LEARY: I'm not interested in your
22 interpretation. What do Reed, Albrecht, Nachtsheim -- what
23 do any of the authors say about why it was represented the
24 way it was in the published article as opposed to the way it
25 was graphed in the preliminary document?

1 MR. SACCHET: I don't recall specific testimony on
2 that question.

3 JUDGE LEARY: It had to be done for some reason,
4 and I'm trying to understand whether or not there was some
5 scientific justification that would have made that graph
6 that was published a better representation or more valuable
7 representation than the actual data.

8 MR. SACCHET: I could proffer.

9 JUDGE LEARY: No, I'm not interested, nobody's
10 commented. The authors of the article have not commented in
11 terms of why the graph was depicted the way it was when it
12 was finally published.

13 MR. SACCHET: All I know is that the Professor
14 Nachtsheim, the professor at the University of Minnesota,
15 analyzed that graph and worked with Mr. Albrecht and said
16 that it should be better portrayed as an average as opposed
17 to a moving average. I do know that.

18 JUDGE LEARY: That's in the record.

19 MR. SACCHET: It may not be in the record that
20 we've submitted because --

21 JUDGE LEARY: That's all I'm interested in because
22 that's all we have to go on.

23 MR. SACCHET: So I'm representing that when I took
24 --

25 JUDGE LEARY: I'm not interested in what you

1 represent.

2 MR. SACCHET: When I took Professor Nachtsheim's
3 deposition.

4 JUDGE LEARY: Okay, if that's part of the record,
5 go ahead.

6 MR. SACCHET: And the documents that were part of
7 that deposition reflect that Professor Nachtsheim preferred
8 to have an average as opposed to what --

9 JUDGE LEARY: This is what he testified to?

10 MR. SACCHET: Yes.

11 JUDGE LEARY: Okay.

12 MR. SACCHET: If questions are finished on that
13 particular topic, I can move into I believe I've touched on
14 the issue of confounding with respect to the
15 thromboprophylaxis.

16 I do want to just note for the Court, I'd like to
17 briefly talk about Professor Holford's testimony regarding
18 the change in start date, which is also one of the topics
19 that came up this morning with respect to the study itself.

20 The time period of the McGovern study occurred
21 from July 1st, 2008, and it ended on January 1st, 2011,
22 approximately a 2.5-year time period. Professor Holford
23 constructed a different analysis in which he said, well, you
24 could have improved the power of the study, and you could
25 have expanded the time period instead of starting on

1 July 1st, moving the date back nine months to October 1st of
2 2007. And when you do that, there's a nonsignificant
3 difference in deep joint infections when that data is
4 included.

5 Professor Holford's argument depends on the
6 reliability of Albrecht Exhibit 10. That's the source of
7 the data in which he conducted his pre-McGovern study
8 analysis. Professor Holford already admitted on the record
9 that Exhibit 10 was incomplete. And, indeed, the authors of
10 the McGovern study testified to the same fact.

11 Dr. Reed, unlike any of the other authors of the
12 McGovern study, was the only one in charge of collecting the
13 data. Mr. Albrecht wasn't in charge of collecting the data.
14 Not even Dr. McGovern was in charge of collecting the data.
15 Dr. Reed said on the record that that was his
16 responsibility, and he worked with a team of nurses at
17 Wansbeck Hospital to gather that data.

18 What Dr. Reed also said on the record is that full
19 surveillance did not start until July 1st, 2008. The exact
20 same date of the McGovern study. When I cross examined
21 Professor Holford on that issue, I said, do you have any
22 reason to doubt Dr. Reed's testimony? No.

23 Dr. Reed also testified that if one were to rely
24 on data prior to July 1st, 2008, "it would be very
25 unreliable because it was incomplete because they did not

1 have full-time surveillance, and there would be large gaps
2 in the data set."

3 In this excerpt, Professor Holford agreed about
4 this proposition. I asked, "So I just want to be clear,
5 based on what you just said it's either possible that full
6 surveillance began on July 1st, 2008, or perhaps even later
7 January 1, 2009." To be honest, I don't know where he
8 pulled that date out of but that's what he said.

9 And I said, "but you nonetheless constructed your
10 model on data that was prior to that time?" "That's right."
11 So Professor Holford admitted under oath that full
12 surveillance didn't start until July 1st or perhaps even
13 later, yet when he constructed his new start date analysis
14 of fabricating the October 1st, 2007, date, he relied on
15 data prior to the start date?

16 Dr. Holford, again, has published numerous
17 articles in which he criticizes others and says so much
18 about relying on complete data because to do otherwise would
19 lead to a phenomena called data artifact. That just means
20 unreliable analysis. That's exactly what he does here, and
21 this excerpt proves that he relied on data that was not
22 complete prior to the start date.

23 3M makes a couple counter-arguments citing an
24 article by Sprowson and the unpublished transcripts, some of
25 which you've seen. What I would like to make clear with

1 respect to the second argument is that in those manuscripts,
2 the McGovern authors expanded the data set as much as they
3 could based on complete data, as opposed to contracting it
4 to contrive statistical significance.

5 In fact, as I've already mentioned, they did a
6 post-publication analysis in which they expanded the data
7 set even further and got the same exact results. So to
8 suggest that the McGovern authors cherry picked a start date
9 in order to achieve that result is belied by the fact that
10 they tried to have as much full data as they could and they
11 expanded the time line accordingly.

12 I asked Dr. McGovern a question point blank, was
13 there any attempt to cherry pick data? Did you try to start
14 this start date at a particular time to achieve that? Do
15 you have any idea of any of that happening? And he said,
16 no, all we tried to do is collect as much as we could as
17 long as it was complete. And Dr. Reed testified to that
18 same fact.

19 THE COURT: Okay. In view of time, I just wonder
20 if you'd be able to wrap up your comments.

21 MR. SACCHET: Of course. It would be helpful from
22 Your Honors if I could know in trying to wrap up, there are
23 two topics I really, really would like to mention which
24 deals with potential confounding from antithrombotic and the
25 double control that Judge Noel had asked so much about in

1 attempting to make the odds ratio disappear.

2 THE COURT: Why don't you go to that because
3 haven't you talked about the antithrombotics?

4 MR. SACCHET: If I said antithrombotics, I meant
5 antibiotic. So antibiotics. Professor Holford curiously
6 never actually says in his report that the antibiotic is a
7 confounder, but what he did do is he included a calculation
8 where he controlled for Bair Hugger patients by only looking
9 at patients, only looking at Bair Hugger patients. And he
10 compared Bair Hugger patients who received the first
11 antibiotic, which is called Gentamicin, to the second
12 antibiotic, which is called Gentamicin plus Teicoplanin.

13 The inference from Professor Holford's report and
14 the arguments that are made today is that a change from
15 Gentamicin was actually better and that the use of this dual
16 antibiotic lead to decreased infection rates and, therefore,
17 contributed to the drop in infection rates that the HotDog
18 patients had the benefit of but only some of the Bair Hugger
19 patients had the benefit of, if that makes sense.

20 Professor Holford's own calculation defies the
21 entire theory. When he controlled for Bair Hugger patients,
22 the risk of infection among those who received Gentamicin
23 the first regime was 1.92 percent. The risk of infection
24 among Bair Hugger patients who received the second regime,
25 almost double, 3.13.

1 So when I saw this report, I really, I had a hard
2 time getting my head around it because his own calculation
3 disproves his own testimony and all of the arguments that 3M
4 had made in this litigation as to the confounding from the
5 antibiotics. So I asked Professor Holford, okay, so wait a
6 second, so couldn't it actually be possible that there was
7 reverse or negative confounding in that patients who
8 received the HotDog and had the second type of antibiotic
9 Gentamicin plus Teicoplanin actually had a worse antibiotic
10 and therefore the odds ratio should even be higher than what
11 was reported in the study? And he agreed. I asked him, so,
12 if anything.

13 THE COURT: Okay. So now you're next point.

14 MR. SACCHET: Fair enough. The double control
15 issue, which is one that's come up also. At the end of
16 Professor Holford's report, he attempts to control for all
17 potential confounding variables by only looking at Bair
18 Hugger patients who received Gentamicin and Teicoplanin and
19 Bair Hugger patients who received Tinzaparin, and then
20 looking at HotDog patients who received the same exact
21 protocol.

22 Now this is important. The McGovern study had
23 over 1400 patients. When Holford controlled for all
24 hypothetical confounding factors, the number dropped to less
25 than half, 640. There were three deep joint infections out

1 of 270 Bair Hugger patients, and there were four deep joint
2 infections out of 372 HotDog patients.

3 In this very case, 3M's 30(b)(6) witness, there is
4 a document that we put in, it's on the record in which he
5 testified that in order to have an adequately powered
6 statistical calculation, you would need more than a thousand
7 patients. Professor Holford's group is 640. He admitted on
8 the record when I deposed him that he did not a rudimentary
9 power analysis.

10 And, in fact, Mr. Albrecht who we've heard about
11 3M's implication that he agreed to the same fact that it
12 disappears. He said the very exact same thing at his
13 deposition but that's never been quoted by 3M. Although,
14 Mr. Albrecht did acknowledge that the rate of infection
15 would be very similar when you control for confounding
16 factors, which is still an increase, although nominal,
17 1.11 percent DGI during the Bair Hugger period compared to
18 1.08 during the HotDog period, that he could not determine
19 the meaningfulness of whether the odds ratio disappeared
20 because the calculation was under-powered. There's not
21 enough patients and that's proven by 3M's own corporate
22 witness. It's vastly under-powered.

23 And to be honest, it's no surprise, if you have a
24 small sample size, and you have a very low rate of infection
25 in order to actually see if there's a meaningful difference,

1 you need a lot of patients, and that's the very reason that
2 3M has refused to conduct the randomized controlled trial.

3 THE COURT: All right. Thank you.

4 MR. SACCHET: Do you want to hear anything about
5 Dr. Borak?

6 THE COURT: We really can't right now.

7 MR. SACCHET: Okay. Fair enough.

8 THE COURT: But you'll be back tomorrow, and we'll
9 consult and actually we'll give you a few minutes to talk
10 about Dr. Borak in the morning, but we have to be in recess
11 now. And we'll come back tomorrow at 9:00 a.m.

12 MR. SACCHET: Okay. Thank you.

13 THE COURT: We're in recess.

14 (Court adjourned at 4:26 p.m.).

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17
18 I, Maria V. Weinbeck, certify that the foregoing is
19 a correct transcript from the record of proceedings in the
20 above-entitled matter.

21
22 Certified by: s/ Maria V. Weinbeck

23 Maria V. Weinbeck, RMR-FCRR
24
25